Exhibit E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Shirley Freeman, et al., Plaintiffs, vs. ETHICON, INC., et al., Defendants.	Case No. 2:12-cv-00490

PROLIFT+M

Tuesday, March 8, 2016

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Deposition of SUZANNE PARISIAN, M.D., held at Marriott Tempe at the Buttes, 2000 West Westcourt Way, Tempe, Arizona, commencing at 9:00 a.m., on the above date, before Alisa Smith, Arizona Certified Court Reporter.

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I N D E X

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EXHIBITS MARKED

EXHIBITS MARKED

SUZANNE PARISIAN, M.D.,
the witness herein, having been first duly sworn by the Certified Court Reporter, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. GAGE:

Q. Good morning, Dr. Parisian.

A. Good morning.

Q. My name is William Gage. I'm with Butler Snow Law Firm. I'll be taking your deposition today.

Could you state your name, please?

A. My name is Dr. Suzanne Parisian.

Q. And your current address?

A. 7117 North Third Street, Phoenix, Arizona.

Q. And, Dr. Parisian, as we discussed before the deposition, we only have three hours under the -- either the court order and/or agreement of the parties, so there may be places where -- and I'll apologize in advance -- where if, you know, counsel will permit, I may sometimes withdraw questions if it looks that your answer is going to be too long or too convoluted, because I would rather move to another subject.

So I apologize in advance for perhaps at

times being curt, but it's because of the short time limit, so -- and I know counsel may not always agree with me, but we'll manage and try to work the best that we can.

A. Yes, sir.

(Whereupon, Exhibit Nos. 1 through 6 were marked for identification.)

BY MR. GAGE:

Q. We've premarked some exhibits.

Exhibit 1 to the deposition is the deposition notice. Exhibit 2 to the deposition is Dr. Parisian's report.

Is that correct, Dr. Parisian?

A. Yes, sir.

Q. Exhibit 3 is a document entitled "List of documents provided or identified for review in the above-referenced lawsuit."

And, Dr. Parisian, you're familiar with that document?

A. Yes, sir.

Q. Document 4 is Dr. Parisian's current CV.

And, Doctor, you agree with that?

A. Yes, sir.

Q. Exhibit 5 is a list of Dr. Parisian's court testimony from January 2011 to January 2016, which

you, Dr. Parisian, provided us; correct?

A. Yes, sir.

Q. And then Exhibit 6 is a collection of documents. It's a composite exhibit. It contains probably a quarter of an inch stack of documents that counsel represented before the deposition started are documents that were obtained, presumably by plaintiffs, from FDA through an open records request, that relate to various issues at the FDA with regard to pelvic mesh.

And, Dr. Parisian, I assume you've reviewed these as well?

A. Yes, sir.

Q. All right. And that collection of documents is marked as Exhibit 6.

All right. Dr. Parisian, with respect to -- with respect to your report, who typed it?

A. Me. All the typos are mine.

Q. Okay. Did you send a copy to plaintiffs' counsel for review before you finalized it?

A. No.

Q. You just wrote it?

A. Yes, sir.

Q. Okay. Is this just one draft?

A. Yes, sir. It's not really a draft. It's a

working copy. And so when I finish it, I send it to them.

Q. All right. And when you sent it to them, did you send it to them signed, or did you send it to them unsigned and then request feedback or comment?

A. Well, I have to -- to sign it, I have to scan my signature, so they're all unsigned, and then I have to scan the signature and send it to them.

Q. All right. So when you typed your report and sent it to plaintiffs' counsel, the version that we are working with today is the same version that you would have sent to plaintiffs' counsel?

A. Yes, sir.

Q. Okay. Are there any other documents apart from your report that -- that you created as part of your work in this case?

A. No.

Q. No spreadsheets, databases, or other data compilations?

A. That's correct.

Q. And are all of the opinions you tend -- you intend to offer in this case contained within the confines of your expert report?

A. Well, it depends what you ask me. I've

tried to summarize them. If there's -- more documents come up, then -- like this document that just came, you know, that's not in my report. So I -- at the time I wrote the report, I tried to capture the information.

Q. All right. And what you're referring to when you talk about "the document" is Exhibit 6; correct?

A. Yes, sir.

Q. So I understand that, you know, you've given us an expert report that's over 100 pages in length, and I may ask you about certain portions of that today, and you may give me additional information or opinions.

Presumably, those will all be subparts, if you will, of what's contained in the document?

A. Hopefully, yes, sir. That's what this is for; right?

Q. Right.

And then you've got Exhibit 6, which is really kind of new and separate and apart from the actual report itself; correct?

A. True. I mean, I knew that there was a working group. I just had never seen the documents from the working group before.

Q. All right. And apart from Exhibit 6, you're not aware of any other document or database or notation of ideas or concepts that you have created or that you would use to provide opinions that are not already contained within your report?
A. That would be -- there actually has been a release by FDA, the reclassification of instruments, and that was just February 26, so there are those documents.
Q. All right. So, Dr. Parisian, you just handed me a collection of documents about maybe a quarter of an inch --
A. Yes.
Q. -- maybe an eighth of an inch to a quarter of an inch high. I'm going to mark those collectively as Exhibit 7.
A. Right. And those are from the FDA's Web site.
(Whereupon, Exhibit No. 7 was marked for identification.)
BY MR. GAGE:
Q. All right. And just looking over those, the document -- first document is entitled, "Reclassification of Urogynecologic Surgical Mesh Instrumentation, FDA Questions," dated

February 26, 2016; correct?
A. Yes, sir.
Q. All right. And then behind that appears to be -- well, there is a document entitled, "Reclassification of Urogynecologic Surgical Mesh Instrumentation," dated February 26, 2016; correct?
A. Yes, sir.
And I mentioned that the FDA was going to reclassify them in my report --
Q. Yes.
A. -- so this has just subsequently come out on the FDA's Web site.
Q. All right. So we'll -- we will talk about this document, which I have now marked as collective Exhibit 7.
Are there any other additional documents or data summaries, compilations of data, of any shape, form, or character other than what we've already discussed?
A. I don't believe so.
Q. Okay. Do you have any plans on supplementing any of your opinions with regard to Prolift+M?
A. Not that I'm aware of.
Q. Dr. Parisian, with regard to Exhibit 3,

which is your list of documents provided or identified for review in the above-referenced lawsuit --
A. Yes, sir.
Q. -- do you see that? --
A. Yes, sir.
Q. -- who typed this document?
A. I didn't type it.
Q. Do you know who typed it?
A. No.
Q. Do you know how you came into possession of it?
A. No. I knew that -- no, I don't.
Q. Okay. Do you understand this document to be -- and I'm speculating here, but I'll throw it out and see what you know.
Do you understand this document to have been prepared by plaintiffs' counsel in this case?
A. Yes, sir.
Q. Okay. And this -- have you reviewed this document?
A. I haven't reviewed it, no, sir.
Q. So you don't know whether this document, Exhibit 3, contains a list of everything that has been provided to you?

MR. JONES: Objection.
THE WITNESS: I don't know that it does.
I mean, in terms of what has been provided, I know that there was -- the people providing me were keeping track of it, and then I cite some different things in my report, and so they're trying to put that in.
I didn't type the list. I don't have any reason to think that it wouldn't contain it, and that's why I brought the documents that I thought may be new documents and not on the list.
BY MR. GAGE:
Q. Do you have a separate list of documents that have been provided to you or which you have reviewed in connection with your expert report?
A. No.
Q. How did you physically receive documents?
A. I received them in folders, these black binders which I brought today, and so that's how I received them.
Q. Okay. So I'm going to just stand up and kind of go walk around on the other side of the table to just take a look at the black folders.
So what you have -- what you've brought with

you to the deposition today are three large black binders that fit into one box, and they have -- one of them is TVT-Secur, so we'll save that one for the next deposition.

That leaves two other binders, and one of those two -- Dr. Parisian, this one at least, when I pick up the first document, appears to relate to Prolift+M. Is that correct?

A. Yes, sir.

Q. So is it fair to say, is the other one Prolift+M or is it Secur?

A. It's 522 -- it's the 522 documents.

Q. Okay.

A. And I think -- I know TVT Secur had been in the Garcia deposition, that black binder.

Q. Yes.

A. I haven't touched it since then, and so that was there at that deposition.

Q. Okay. Well, I'll tell you what. So that I don't forget it, I'm going to put the TVT Secur notebook on top of my TVT -- I'm going to give it back to you, but I'm going to put it over here so that when we take this deposition, hopefully I'll remember to ask you about it. If I don't, maybe you can remind me.

A. Okay.

Q. All right. So with regard to Prolift+M, we have two notebooks here. One you're saying relates primarily to the 522 issues?

A. Yes, sir.

Q. And the second of which is just really kind of your general Prolift+M documents, and I also see that you've got some notes in here too. Is that correct?

A. Yes, sir.

(Whereupon, Exhibit Nos. 8 and 9 were marked for identification.)

BY MR. GAGE:

Q. All right. So why don't we mark as Exhibit 8 this notebook that you've given me that contains a lot of handwriting, a lot of sticky notes, and then a lot of photocopied documents.

And I'll ask you, Doctor -- and then we'll mark as Exhibit 9 the notebook that you told me relates primarily to the 522 orders.

And Nate and Bryan and I will figure out later how we photocopy this because I hate to create a gigantic depo with a gigantic amount of exhibits, but we'll figure out --

MR. JONES: The best way, the easiest

way we can.

MR. GAGE: Yeah, We'll figure out a way, and I will definitely want to get a copy of this, but I know we don't really have that -- I don't think we have that ability to do it today.

MR. JONES: I think we can work together to find a solution.

MR. GAGE: But, Counsel, can I ask that I have a copy of all the handwritten notes and the stickies?

MR. JONES: You will get that binder, absolutely.

MR. GAGE: Perfect. Thank you.

And the same for Exhibit 9 as well and the TVT-Secur. Okay. Thank you.

THE WITNESS: And then these are documents that I went and pulled, too, that relate to the Prolift+M, so some of those are mine. That's my file, so you have my file.

(Whereupon, Exhibit No. 10 was marked for identification.)

BY MR. GAGE:

Q. All right. So that -- so Dr. Parisian's handed me a folder, a red folder, that's probably two inches thick --

A. Yeah. I guess so, yeah.

Q. -- about two inches thick of documents that Dr. Parisian -- Dr. Parisian, did you identify this as your file?

A. Yeah, that's my file. Not everything fit in the notebook.

Q. Okay. So these would just be documents much like those found in Exhibit 8, but they just wouldn't fit inside of that notebook --

A. Correct.

Q. -- that we've marked as --

A. And they weren't sent to me. I went and got them.

Q. Okay. That's -- that's important.

A. Right.

They're not that -- they're not that exciting of documents, but I just wanted you to have the whole thing.

Q. Was everything in Exhibit 8 provided to you by plaintiffs' counsel?

A. Yes, sir.

Q. Was everything in Exhibit 9 provided to you by plaintiffs' counsel?

A. Yes, sir.

Q. And everything in Exhibit 10 were documents

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that you got on your own?
A. Yeah. Miscellaneous documents, yes, sir.
Q. Okay. And then the documents that we talked about that were part of Exhibit 6 from FDA, those were provided to you by plaintiffs' counsel; correct?
A. Yes, sir.
Q. What about Exhibit 7, the reclassification documents?
A. No. I went and got those.
Q. Okay. So Exhibit 7 and Exhibit 10 are the -- would it be correct to say that what is found in Exhibit 7 and Exhibit 10 are the only documents that you have gathered on your own accord in connection with your opinions on Prolift+M?
MR. JONES: Objection.
THE WITNESS: I believe that's correct, because I think -- I mean, obviously, I referenced the guidance documents, like the surgical mesh guidance and the -- and I believe they're in those black folders.
But I would have gotten my own 510(k)s, and -- and some of them are in there, but some of those guidance documents I think are -- I just didn't want to be duplicative.

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BY MR. GAGE:
Q. Okay. So what about medical literature? If I wanted to know every piece of medical literature that you reviewed in connection with your opinions on Prolift+M, where would I go to find that?
A. Some of it would be in the black folders. I don't have a file for medical literature for Prolift+M. So a lot of it would have come from the folders -- would have been in the black documents that were given to me.
Q. And if counsel -- if the list that's marked as Exhibit 3, what we sometimes call the reliance list, is accurate, it would presumably contain every document that is in Exhibit 8?
A. It should, yeah. I would expect it to.
Q. Okay. So the universe of medical literature that you reviewed would either be in Exhibit 3, or if maybe counsel made a mistake and didn't type it up, it would be in Exhibit 8?
A. Yes.
Q. You do not have a separate stack, pile, or collection of medical literature that you reviewed for the Prolift+M case that is apart from what you've handed me today?
A. No. And if you look in the red folder,

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there are some things that I got from -- from my search of the national medical library, blood work, abstracts, and so those are in there.
So see -- there they are, the abstracts and stuff, because some of them are in French -- so you would have it all.
Q. Okay. As I look through -- as I'm looking through the documents in Exhibit 10, I see the deposition of Marty Weisberg from November 2015, I see Prolift+M FDA 510(k) timeline, 522 Order and re-commercialization. I see some information about ENDOLOOP?
A. Right, because I talk about ENDOLOOP in my report, so those are the documents I pulled.
Q. Okay. I see some stuff about ARTISYN. I see some information about -- some information you pulled back on the MAUDE database. Is that correct?
A. Yes, sir.
Q. And then I see a document called Summary of Care for Carolyn Moorehead?
A. Right.
Q. What is that?
A. That was how I originally got this. It was going to be Ms. Moorehead's case, Prolift+M. I think they -- I don't know -- I don't know what

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happened to Ms. Moorehead, but that's what I received.
Q. All right.
MR. GAGE: I would -- I would ask counsel, plaintiffs' counsel --
MR. JONES: Just for the record, I think that's related to her prior involvement in the TVT-Secur case, and so I think she's trying to be -- over-sharing perhaps in giving her complete file and anything -- so if that's part of her complete file, and so we'll take that out and make sure that's not in the final exhibit.
MR. GAGE: I think, unless you guys disagree, the document that I am looking at is purely -- it's about a seven- or eight-page document. It appears to be --
THE WITNESS: Just medical history.
MR. GAGE: -- exclusively related to one plaintiff, and it goes into quite a good bit of detail about her individual health.
MR. JONES: Absolutely.
MR. GAGE: What I would recommend is -- I would like a copy of it, but I do not believe it should be marked as an exhibit unless you're prepared to redact almost everything out of it,

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because I don't think that this needs to be generally circulated with her deposition transcript.
MR. JONES: Correct.
MR. GAGE: We agree to that?
MR. JONES: And I think what might be the best approach is for me to go through that particular exhibit prior to it being formally marked, and like you said, give it a careful read and make sure there's no information in there that shouldn't be in there.
MR. GAGE: I don't -- you know, if somebody wants a copy of the deposition of Dr. Parisian that we've taken, I would like to be able to give it to them without worrying about somebody's very specific --
THE WITNESS: Should I give it to him and have him look at it?
MR. GAGE: I mean, I would like a copy of it, and I think as counsel I can look at it, but I don't want it to be part of the record that gets moved around.
BY MR. GAGE:
Q. All right. All right.
So, Dr. Parisian, let me ask you this about your reliance list.

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A. Um-hmm.
Q. You indicated earlier, I believe, that plaintiffs' counsel provided you with some documents to review. Is that correct?
A. Yes, sir.
Q. Did you ask for any additional documents from plaintiffs' counsel?
A. I asked for any FDA-related documents, and that was why they gave me the document that we have now -- is that Exhibit 6 or --
Q. Is it Exhibit 8?
A. No. It's the one you just got today.
Q. Exhibit 6?
A. Yeah, Exhibit 6. And that's how I happened to come upon it, because I said I wanted anything FDA-related, and so they gave me that.
Q. All right. So Exhibit 6 was not in the stack of documents that they originally provided you; correct?
A. That's correct.
Q. And then with respect to the documents that are on your reliance list, do you know who made the determination as to what to send to you?
A. No.
Q. Presumably, it would have been somebody with

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plaintiffs' counsel; correct?
A. Right.
Q. Apart from Exhibit 6, did you ever go through your documentation that was provided to you by plaintiffs' counsel and ask them to send you anything else to review in connection with your Prolift+M opinions?
A. I don't think so.
Q. Okay. Exhibit 4 is your CV, and I assume it is current?
A. Yeah. Yes, it is.
Q. Exhibit 5 is your list of court testimony from January 2011 to January 2016.
I assume the definition of court testimony, this is every place that you've ever been deposed or testified live at trial during those -- during that time period. Is that correct?
A. Yes, sir.
Q. And is that -- is this list current and accurate and correct?
A. Yes, sir.
Q. Let me ask you this before I forget. You have been asked at prior depositions if you have -- if your testimony has ever been excluded, and I know there have been a couple of occasions that you've

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indicated.
Are you aware of any time in the last two years where your testimony has been excluded for any reason?
A. No.
Q. Okay. So the instances where your testimony has been excluded, at least to your knowledge, predate the last two years?
A. Yes.
Q. It would have been -- it would have been sometime earlier than 2014?
A. Yes. And by excluded, I'm not saying -- sometimes a judge will say, "You can't talk about this. You can't talk about that," but we're talking about excluded where I didn't go to court and stuff, and I only know of maybe one time.
Q. All right. And Exhibit 7, which was the reclassification documents, you pulled those yourself off the FDA Web site. Is that correct?
A. Yes, sir.
Q. All right. And the original document that you handed me has your highlights on it?
A. Yes, sir.
MR. GAGE: So, Nate, as we set about the task of photocopying these things, I would ask

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that the highlighting be --
MR. JONES: Yeah. You will get them as produced.
MR. GAGE: -- replicated as they're produced.
BY MR. GAGE:
Q. All right. So, Dr. Parisian, I'm on Exhibit No. 8, which is the notebook of documents.
And I think, if I'm remembering correctly, you've testified this is largely a printoff or a printout of documents that were provided to you by plaintiffs' counsel. Is that correct?
A. These were the only documents that were provided to me.
Q. Okay. Were they provided to you in the form of a notebook, on paper, or were they provided to you on a disk or some other electronic means?
A. In a notebook. You have them as -- that was how they were provided.
Q. Okay. So the actual document, Exhibit 8, or the actual Exhibit 8 is the actual notebook that plaintiffs' counsel actually provided to you?
A. Yes, sir.
Q. Okay. And apart from this -- apart from Exhibit 8 and Exhibit 9 -- well, let me -- actually,

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strike that.
Was Exhibit 9, is it -- was it provided to you in this form?
A. Yes, sir.
Q. Okay. So when I'm holding Exhibit 9, this is the actual notebook that was actually provided to you by plaintiffs' counsel?
A. Yes, sir.
Q. Okay. And Exhibit 8 contains a good bit of handwriting.
I assume all of the handwriting in this is yours?
A. Yes, sir.
Q. And I assume all of the stickies are yours?
A. Yes, sir. And there's no color coordination.
Q. Okay. And the highlighting is all done by you?
A. Yes, sir.
Q. And this was all done after you had been retained and before you wrote your report?
A. Yes, sir.
Q. Do you have any plans on doing any additional work with respect to Prolift+M?
A. No, sir.

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Q. Are you waiting on any information which might cause you to alter your opinions in this case?
A. No, sir.
Q. Have you -- is there any pending request to plaintiffs' counsel for additional documents or information that you are waiting on with regard to Prolift+M?
A. No, sir.
Q. I may have covered this earlier, but I'm not sure it's clear in my mind, which means it may not be clear in the record.
With regard to medical literature, I think you -- that you have reviewed in connection with this case, as I understand, it's come from two sources. It's either going to be in one of the exhibits that we've already marked that came from plaintiffs' counsel, or it's going to be in Exhibit 10, which is a collection -- which includes some documents that you yourself gathered; correct?
A. Yes, sir.
Q. I saw that there were several depositions on your reliance list.
Did you read those?
A. Yes, sir.
Q. Did you read all of the documents on your

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reliance list?
A. Well, let's -- which ones specifically are you asking me of?
Q. Well, let me ask you this.
A. I don't remember reading them all. I looked at parts of them. I wouldn't say that I've read every single word of every one of them.
Q. Okay. So, for example, when I look through Exhibit 8 and Exhibit 9 and Exhibit 10, I don't see any deposition transcripts, but I see deposition transcripts on your reliance list.
A. Right.
Q. Can you tell me where those deposition transcripts are and how you received them?
A. No, because I don't -- I don't have them sitting on my computer. If they're not in there, I haven't reviewed them.
Q. Okay. So --
A. And I don't think I cite most of them in terms of my report. The ones that I've reviewed I cite in my report. Because I know -- I know who some of these people are, but I haven't read them all, so I don't know where they are.
Q. All right. So if there's a -- the only depositions that you would have read would be

depositions that you specifically cited to in your report. Is that correct?
A. Yes, sir.
Q. And if there's a deposition that appears on your reliance list, which is marked as Exhibit 3, that is not cited in your expert report, then it means that you did not read that deposition. Is that correct?
A. I haven't read all of those depositions, no, sir. That's correct. I know who some of these people are but did not read all their depositions.
Q. Okay. So for the depositions that you did read --
A. Um-hmm.
Q. -- where are they physically located?
It was my understanding you had given us everything that you physically had in your possession, and I don't see any deposition transcripts. And I'm just wanting to know, where are those transcripts?
A. You know, I don't recall. I don't recall. I didn't look at my computer last night to see if there are depositions on that. I can go look and see and update you as to what ones I have.
Q. Okay.

A. But I don't -- I didn't look at it last night to see if there's any depos on there.
Q. All right. So I would ask for you to visit with counsel and to give us --
A. Any depos that I've been sent?
Q. -- any depos that you've been sent.
A. Okay.
MR. JONES: And I'll just tell you, I didn't print off the depositions for you. I can go do that if that's what you're wanting me to do, but they're not -- the printed 500-page long depositions are not in those binders. We'd have about 20 binders.
MR. GAGE: Yeah. I think what I would like to have, if it's okay for you, Nate, and Dr. Parisian, is if you guys could just send me a document that says, "Here are the deposition transcripts that I, Dr. Parisian, reviewed" -- I guess it would fall into two categories: "Here are the transcripts I received and didn't review. Here are the transcripts that I received and did review."
THE WITNESS: Okay.
MR. GAGE: And then just sign your name, "Before I" -- "Before I signed my Prolift+M report" --

THE WITNESS: Right.
MR. GAGE: -- if you could provide me -- would y'all be willing to give me that one page?
MR. JONES: We'll talk about it and see what we can do, but we'll work on that.
MR. GAGE: Okay. Because I'm going to need something that has the witness's --
MR. JONES: Correct.
THE WITNESS: Right. I can do that. Because I didn't look on my computer last night. That's why I can't answer the question.
BY MR. GAGE:
Q. That's fine.
But I just need -- just for posterity and for the depo, I'll need something -- I'll need a document that you have approved and agreed to --
A. Right.
Q. -- with regard to that issue, so I'll make that request --
A. Right.
Q. -- and we'll work with Nate to get that.
A. So you will know who I've read.
Q. Exactly.
Have you read any expert reports from any

expert witness in this litigation?
A. I know I've read Dr. Miklos' report, but that's our side, isn't that?
Q. Yes.
And I believe was that in connection with your TVT-Secur opinions in the Garcia case?
A. I think so, yeah.
Q. Apart from Dr. Miklos' expert report, have you read any expert reports from anyone else in the mesh litigation?
A. I don't think I have.
Q. And I'll represent to you, I didn't see any in these documents. But in -- as I ask -- as I just asked for the list of deposition transcripts, if you -- when you go back to your computer, if you see that you have received and didn't review expert reports or if you received and did review expert reports, I would ask that you add that to the list.
A. I don't recall reviewing any expert reports for Prolift+M.
Q. Have you spoken to anyone who you understand to be an expert in this litigation?
A. No.
Q. And, Dr. Parisian, as I understand it, you have served as an expert witness for plaintiffs in

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mesh cases other than those involving Ethicon or Johnson & Johnson. Is that correct?
A. Yes, sir.
Q. And is it correct to say that anytime you've either testified live in court or been deposed would be reflected on the list of testimony that you gave us?
A. That five -- I did -- I don't think on that list would be the ProtoGen. I did ProtoGen, depos in that. That was a long time ago.
Q. But that wouldn't be on the list because the list has a cutoff?
A. Right. It's five years.
Q. Right.
A. And then the other thing would have been I was in a case against Johnson & Johnson with an attorney, Ray Putney, that had a sling that had been placed, and a woman had a bone anchor that was pre all this stuff. It was be- -- and so there was an early case against Johnson & Johnson in Texas --
Q. Do you remember --
A. -- and so those wouldn't be in the two -- in the lists that you have.
Q. Do you remember what product was involved in that case?

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A. It was -- it was -- well, it was Johnson & Johnson's sling, and it was a bone anchor. I think a Mitek bone anchor, and I think it was a PROLENE sling.
And it was being done -- this is before they had clearance for this, and that was in Texas. I know the attorney's name is Ray Putney, and I don't remember what the woman's name was. I think --
Anyway, so -- but Johnson & Johnson had actually been in the OR when she was having all this implanted, some of their executives and stuff.
Q. Do you know if this was a TVT or a TVT-O?
A. Oh, no, no, no. It was pre -- it was before TVT. So it was actually something that the company was looking at before they did their TVT.
Q. So this is something that predates -- an implant that would predate 1998?
A. Yeah, yes.
Q. All right.
A. And so that went to court, and then it settled, and so that's not on that list.
Q. All right. Have you ever testified in a mesh trial?
A. Yes. Boston Scientific, a trial in, I think, Delaware or Rhode Island for Motley Rice.

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Q. And that was within the last couple years?
A. Yes, sir. And that's on my history.
Q. All right. And you've never been charged with a crime of any type; correct?
A. No, sir. Thank goodness.
Q. Who actually retained you for your Prolift+M work?
A. Lee Lundquist for Clark, Love & Hutson.
Q. Had you ever worked for them before?
A. Yes, sir.
Q. Can you just give me some details about the nature of the relationship with Clark, Love before you were asked to opine on Prolift+M?
A. I had worked with them on -- the Garcia case was with them, and I had worked with them -- many attorneys I work with are part of the MDL, and so they had been -- I originally met them in Paxil when I was involved with Paxil litigation. And then I met them again when I was involved with Trasylol, but -- so the only times I was working for them specifically was for mesh, and that was for Ethicon.
Q. How long did you work for them on Paxil?
A. Paxil is still going on.
Q. Are you still doing work for Clark, Love in Paxil?

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A. No. I'm doing -- no, no, but Paxil, it's still going on. They don't go away.
Q. Are you still doing work for anyone for Paxil?
A. Yes.
Q. But not Clark, Love?
A. No. They're out, but it continues on.
Q. All right. Do you have any documents or invoices reflecting compensation in this case, either amounts billed and not paid or amounts billed and paid?
A. You know, I didn't bring that. I did bring my worksheet for just the last couple days which we haven't billed for yet.
Q. All right. Dr. Parisian's handing me a document that we'll mark as Exhibit 11.
(Whereupon, Exhibit No. 11 was marked for identification.)
BY MR. GAGE:
Q. And this is a single sheet of paper that at the top says, "Wagstaff & Cartmell. Attention Jeff Kuntz, Attorney, re: Ethicon," and it reflects two hours of work -- I'm sorry -- it reflects several hours of work on March 6, 2016, and then several hours of work on March 7, 2016?

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A. Yes, sir.
Q. Okay. And I take it this is just an itemization of the amount of time you've spent over the last two days?
A. Right. Yes, sir.
Q. Okay. Do you have an itemization of how much time you spent before March 6 on Prolift+M?
A. I believe there was a bill, and I don't -- I didn't bring the bill. I didn't look at the depo notice. I didn't bring the bill.
Q. Okay.
MR. GAGE: So I'll ask Nate and you to provide that to us.
MR. JONES: Yep, we'll provide it.
THE WITNESS: And that was sent to Clark, Love & Hutson, so I just didn't think of it.
BY MR. GAGE:
Q. Would that bill contain all of your time for fees and expenses apart from Exhibit -- what's been listed in Exhibit 11?
A. Yes, sir.
Q. All right. You don't happen to know or recollect how much that amount was in the invoice that you will be producing to me?
A. No, sir. Because I don't make out the

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billing, so I don't know how much it was.
Q. Can you estimate how long it took you to draft your -- or to review materials and draft your Prolift+M report?
A. No. With the bill, I could probably, but I don't have it in front of me, so I don't know. It took a while.
Q. Do you have an estimate of how many hours you've --
A. No.
Q. -- spent on Prolift+M?
A. No.
Q. But that would be reflected in the invoice to Clark, Love?
A. Yes, sir.
Q. Okay. So if I add whatever's in that invoice to Clark, Love to Exhibit 11, I'll have the entirety of everything that you have billed and/or worked with regard to Prolift+M in this case?
A. Yes, sir.
Q. Can you recollect, even if it's just by estimate, how much time you spent reviewing documents as opposed to how much time you've spent actually drafting your report?
A. No, because I'm doing both at the same time.

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I'm going through the book and drafting at the same time, so it's not like I broke them out separate.
Q. Have you traveled anywhere for purposes of gathering information or for working on your Prolift+M --
A. No.
Q. -- report?
Have you watched any videos?
A. No.
Q. Have you conducted any interviews?
A. No.
Q. Dr. Parisian, I read your TVT-Secur report in Garcia -- I'm sorry -- your TVT deposition in Garcia.
A. Right, because there was no report. It was only disclosure.
Q. Right.
So I read your deposition there, and that deposition was in February of 2015, so from time to time, I may ask you some questions that appear to be duplicative, but the reason I ask them is because there's been a passage of a year and I just need to make sure that something hasn't changed since you last testified about some issues that are general in nature.

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In that deposition, you indicated that you had made over a million dollars over the last five years doing litigation work.
Do you recall that testimony?
A. I think the defense actually indicated it was a million.
Q. Did -- had you made any sort of calculation on that?
A. No, I haven't. Every year I've worked I've given the numbers, so it's no problem for defense to sit there and add up the numbers.
Q. Right.
A. And so I think the defense brought up that number. I don't know what it is. I mean, I haven't hidden anything. And last -- so --
Q. Well, do you know what the -- since I'm trying to stitch together what happened in 2015 so we can bring that testimony forward, can you give us an estimate of the total amount you've earned doing litigation work in 2015?
A. In 2015, it would have been about 700,000. That's how much the company brought in. I didn't keep all that. But I'm trying to cut back. That's what I testified in the depo, too, is I'm trying to -- actually, I was trying to retire, and so it's

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coming down, but not yet. But that was what it was last year.
Q. Can you break out that $700,000 for me and just generally attach your earnings to various pieces of litigation that you've worked on in 2015?
A. You mean --
Q. So, for example -- I'm just giving you an example -- "In 2015, I made 150,000 from mesh. I made 150,000 from Plavix."
A. No, I can't do that. I didn't do Plavix either, so, no, I can't really figure out which -- you have my list, so -- you know, of all the cases I've had.
Q. Do you know how much you've earned working on the mesh litigation?
A. No. At one time I figured it out, but I haven't done it recently.
Q. Can you give me an estimate of what percentage of time in 2015 you spent working for any mesh claim?
A. No, because as you know, I've done mesh for a long time. I mean, with the -- I don't even know what year AMS settled and all that stuff, so I've been working on mesh for years. I did not figure up the time, but I've been doing it longer than one

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year.
Q. In 2015, I know I've got the places where you've testified, but can you itemize for me the various pieces of litigation where you're serving as an expert witness in 2015 irrespective of whether you've actually testified?
A. Usually the deposition list will talk about what -- what I've been involved with because I really am trying to cut my cases back. And so the things I gave depositions are probably the active cases that I had.
Q. You don't -- do you recall any work that you did in 2015 for any piece of litigation where you weren't deposed?
A. No. It seems like you write a report, and then they want to depose you, so, no.
Q. So if I looked at your list of depositions, that would give me an accurate picture of --
A. Let me look at it before I answer.
All right. So I said my depositions; right? So are you wanting to know what I'm active in right now?
Q. Yes.
A. Is that what you're wanting? Okay.
Why don't we do it that way, because some of

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the cases I've been involved in are not active anymore.
Wright Medical, that's a hip implant. Yes, I'm still active in that. AMS pelvic mesh, that is not active right now as far as I know.
Q. Is that because of a settlement?
A. Yeah.
Mirena, I'm still active in Mirena, which is Bayer. The second case there would be a Bayer case, same thing, Mirena. So all the American Medical stuff is gone. Yasmin and YAZ, that's gone. They're not doing that one anymore as far as I know.
PLEVA, I think the PLEVA cases are gone. The generic Reglan cases as far as I know. C.R. Bard, I am active in C.R. Bard. Those are the IVC filter cases, so those would be things I'm still active in.
Ethicon, Wright, so those are -- those are basically what I'm active in now. Let's see. Anything else? Abbott Laboratories, that's Depakote. That's a birth defect case. I'm still active in that. So -- Boston Scientific, yes, I'm still active in that mesh, but only for Motley Rice.
And the Zometa and Aredia litigation, I don't know what's going on with that stuff. I think

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all the ONJ cases are kind of gone. There's some hip fractures cases that may be occurring.
And so those are the main active -- I have fewer cases now than I used to, yeah, so those -- those would be the ones that I'm active in.
I don't know what's going to happen with Fosamax and the hip fractures.
Q. All right. Thank you. That was helpful.
A. Okay. So those are the witnesses I'm still -- and Paxil came back, so I have Paxil again. Apparently, it's re- -- come back. And then Kugel Mesh came back. And so there's some Kugel Mesh cases, and there's actually still one or two HRT cases, hormonal placement therapy.
So I'm trying to cut -- so I have it down to like less than ten.
Q. All right. Have you published any of the opinions you're offering here today?
A. No.
Q. Have you spoken with any scientist, engineer, or medical doctor regarding your opinions?
A. No.
Q. Is it correct to say that you developed these opinions specifically for this litigation?
MR. JONES: Objection.

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THE WITNESS: Well, not -- it isn't really, because, I mean, I've been involved with -- the opinions about Prolift+M, yes, but as you know, I've been involved in this type of issue for other products.
BY MR. GAGE:
Q. Is it fair to say that your opinions were not developed for some research project or study that you are involved in?
A. Yes.
Q. Is it correct that you are not offering any opinions on general causation or specific causation?
A. And I'll qualify that. That to me means like medical causation for a particular plaintiff because, obviously, I think that Prolift+M could contribute. There could be complications like what is seen in a patient.
But I don't see my role as a clinician in terms of a particular case giving medical causation.
Is that what you're asking?
Q. Yes.
I will say that in the TVT-Secur deposition, you answered that question or one similar to it by saying that your opinions would be further developed once you had reviewed the plaintiffs' medical

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records.
MR. GAGE: Can -- and I suppose I should -- I suppose I should have asked counsel if they're willing to stipulate that Dr. Parisian will not be reviewing plaintiff medical records and offering case-specific opinions?
MR. AYLSTOCK: So stipulated.
MR. JONES: Yeah.
MR. GAGE: Okay.
MR. JONES: That's not in our plans.
THE WITNESS: Yeah.
And I look at it as the timing because usually why I review the records is the timing because a judge would want a case to be relevant to that particular patient.
And so I'm not the causation, but I'm looking at it, in terms of testimony, the period of time.
BY MR. GAGE:
Q. Okay. So, for example, if there were multiple IFUs, for example, in Prolift+M, you may look at the medical records in order to determine which was the applicable IFU. You may look at the medical records. You may look at the depositions.
But it's not your intent to then provide a

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case-specific medical causation opinion?
A. That's correct.
Q. Okay. I also did not see anything in your report about any manufacturing defect opinions, where you would be offering an opinion that any particular lot of Prolift+M had a manufacturing defect. Is that correct?
A. That's correct. I've offered that in other cases but not for this one.
Q. All right.
A. And, again, if -- that would be if there is actually a specific plaintiff and I happen to look at their lot, and then I would go look at -- and so that's the one time that I did that in an AMS case.
Q. What was the opinion in summary that you provided for a specific lot in a case?
A. It was a specific lot in that the -- it was in Texas, and it had been kept out in the sales rep's car, and so it had gotten hot.
And then we went back and looked at the device history record. There had been a lot of problems with the manufacturing of that particular lot. So I went through the case reports and the design history and manufacturing, and there -- most of the lot had been rejected.

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And so this was a particular case where this one was like, what? Why did you let that go?
Q. And for Prolift+M, at least to date, you have not been asked to do such a case-specific analysis?
A. That is correct.
Q. You're not here as a representative of FDA; correct?
A. That is correct.
Q. Not speaking on behalf of FDA; correct?
A. That is correct.
Q. FDA has not reviewed or endorsed any of your opinions in this case; correct?
A. That is correct.
Q. Have you ever spoken with anyone from FDA regarding your opinions in this case?
A. No, and I would think that I would be precluded from that, too, but I have not.
Q. Have you ever called or written to FDA about any of your opinions in this case?
A. No.
Q. Were you invited by FDA to be part of a 2011 advisory committee concerning pelvic mesh?
A. No.
Q. Do you know why not?

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MR. JONES: Objection.
THE WITNESS: No, I don't know why not. I wouldn't have put my name out there to be on it. For one thing, I'm not a urologist. I'm not a biomaterials person. And I just have not put myself out there where I would be that expert for that panel.
BY MR. GAGE:
Q. Have you ever been invited by FDA to be on an advisory committee of any type?
A. I was at a meeting, an advisory meeting, to talk about device labeling, and so I was asked to come and talk about that. The FDA was trying to standardize device labeling to drug labeling, so that was -- and it's on my CV.
Q. Do you remember what year that was?
A. Oh, gosh. '97, '98. It wasn't recently. I'd feel very conflicted if I go to the FDA just because of all the stuff that I'm in, and it's better not to talk about anything.
Q. Did you testify at that committee meeting?
A. I was actually on the panel, so there is a transcript with my testimony in it.
Q. Do you know where that transcript is?
A. No. You probably could get it through -- at

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the FDA.
Q. All right. Have you ever seen that transcript?
A. No.
Q. Has anybody ever cross-examined you with that transcript?
A. No.
Q. All right.
A. I know what I said, and, so, no, I didn't --
Q. Recognizing that we have -- we're under a tight time limit, can you give me a summary of what you testified to at that meeting that is less than 30 seconds in length?
A. They were -- yeah, sure.
They were trying to make device labeling like drug labeling, and there were difficulties in terms of that. In terms of writing an adequate device label, it's tricky compared to a drug label, and so that was my -- my discussion was the difference between a drug label and a device label.
Q. And, again, in a summary fashion, what are the differences in your opinion?
A. It's -- it's just -- there's -- it's just a drug label is fairly standard. It's a pill, and you give the same kind of information over and over.

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Whereas, devices, there's all kinds of devices, so you're going to have problems if you try to make it the exact same format.
Q. Dr. Parisian, I know that some of this was touched on during your TVT-Secur opinion, but I'm concerned that it may have been -- some of it in the context of Secur and not Prolift+M, so I'm going to re-ask some of these questions.
At FDA were you ever involved with Prolift or Prolift+M?
A. No.
Q. Were you ever involved with any mesh products for pelvic organ prolapse?
A. Not that I recall. I don't -- I don't recall.
Q. When you were at the FDA, were you ever involved with mesh stress urinary incontinence devices?
A. I don't think so, because I was there -- I left FDA in '95, and so the birth of mesh actually came after that. I've been involved with mesh but not necessarily for SUI. I've gone to meetings, I think at the NIH, about SUI issues but not specifically for this type of issue.
Q. While you were at FDA, were you ever

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involved with pelvic floor repair devices?
A. Not devices, no. I had gone to meetings talking about pelvic floor repair but not devices.
Q. After you left FDA, is it correct to say that you had no involvement with FDA's review of Prolift or Prolift+M or any of the mesh devices?
A. That's correct.
Q. Have you ever drafted a label or an IFU for a surgically implantable device?
A. In clinical trials.
Q. What was that device?
A. It was a device that was being used as a shunt in the brain, CNS shunt, and it was being used in elderly people to try to do clinical trials for Alzheimer's disease, and that's the only one I can recall, and I was a consultant.
Q. What was the company?
A. It was Stanford University. They were trying a clinical trial, so it wasn't a company per se.
Q. So it was a medical device that they had created and wanted to run some clinical trials on?
A. Well, they had me help them create the medical device, and then they wanted to run some trials to see if they could reduce Alzheimer's

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spread, and so I was involved with them.
Q. Did you help create an IFU?
A. For the investigators, yes, sir.
Q. Where could I get a copy of that?
A. I don't know if you can. It was an IDE, and I don't think it really took off. I don't know what happened to it.
Q. Do you have a copy of it?
A. I don't have a copy of it. It was back in, like, '96.
Q. There was some discussion -- well, there was some discussion during your TVT-Secur deposition of your working for a company called "Insurex."
A. SURx, yeah, S-U-R-x.
Q. S-U-R-x?
A. Right.
Q. Right. I think that transcript incorrectly called it "Insurex," I-n-s-u-r-e-x.
A. No. You will never find it. S-U-R-x.
Q. S-U-R-x?
A. It's a radiofrequency device for using a radiofrequency current to try to control a woman's SUI, in terms of that, so -- and I was brought in as a consultant because they had gotten rejected by the FDA, and I was to come in and help clean up the data

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so they could get cleared.
Q. Do you recall what year or years that occurred?
A. No. It would have been, like, in the '90s. It was when I first left the FDA.
Q. Did you assist that company in drafting instructions for use for that device?
A. Yes. But more importantly, I had to look at their data because that was the issue that they had gotten in trouble with with the FDA. So we cleaned up their data.
I don't remember if it was PMA or a 510(k), but it got cleared.
Q. Do you -- did you in that case review or comment on the IFU?
A. It was a training manual, yeah, so I looked at the training manual because you have to be able to comment on how doctors can do it. My main focus, though, was the clinical data.
Q. Did you provide edits or input to the training manual?
A. Yes. I looked at it and gave what my thoughts were, but in terms of -- again, it was the data that I had to look at.
Q. Do you have a copy of that training manual?

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A. No.
Q. Do you know where I could get a copy of it?
A. No. I don't even know if the company is still making it or if they sold it.
Q. Have you ever drafted a patient brochure for a surgically implantable device?
A. At the FDA I commented on them in terms of surgically implantable devices. I have not drafted it from square one. But in terms of medical devices, you're often more interactive with companies in terms of -- like, I know I was involved with implantable cardiac defibrillators when they first came out and also some of the -- so those would have been issues that I was looking at the labels, but I didn't draft them.
Q. Do you -- could you identify for me any -- and I assume while you were at FDA you also looked at and commented upon instructions for use with regard to medical devices?
A. Yes, sir.
Q. Is there -- can you identify for me any instructions for use or patient brochures that you reviewed, edited, and/or approved while you were at FDA?
A. That's really hard. I don't know, I mean,

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because I -- that would have been my routine to look at the IFU and make comments because I looked at IFUs post market for people who needed warnings and had gotten into safety issues and looked at them premarket.
I remember being involved with Cook Catheter. They had an amniotic -- chorionic villus sampling device. I remember working on that in terms of the approval. That was a PMA product. That would have been there. But, no. That was -- routine exam was that you would look at the labeling and make comments.
But more in postmarket, when people got into recall issues, I would always say, "Put a warning," or do stuff, so it would have been more in my postmarket days.
Q. Dr. Parisian, I know much of this was covered at your prior deposition, but, again, it's been a gap of a year's time, and I want to make sure nothing has changed.
Are you still a licensed medical doctor?
A. Yes.
Q. And you are a pathologist; correct?
A. Yes.
Q. You have not gotten any new certifications

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or training in the last year since you were deposed in the Garcia case?
A. That's correct.
Q. Have you treated any patients since 1988?
A. Not as -- I've treated my family, but not as a -- no, I don't have a clinical practice.
Q. All right. And do you have any current board certifications?
A. Yeah. I'm board certified, anatomic and clinical pathology.
Q. Any staff privileges at any hospital?
A. No.
Q. Are you credentialed at any hospital?
A. No.
Q. Did you ever participate in a cadaver study regarding any mesh device?
A. No. A lot of cadavers but not with mesh.
Q. Ever participate in any animal studies regarding any mesh device?
A. No.
Q. Ever design any clinical trials or protocols or studies regarding any device involving mesh?
A. No.
Q. Ever involved in any clinical research regarding mesh?

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A. No.
Q. Ever designed mesh?
A. No.
Q. And I think you testified earlier you've never done any biomechanical testing of mesh. Is that correct?
A. That's correct.
Q. No lab work regarding mesh?
A. That's correct.
Q. Have you done any testing of a polypropylene or mesh explant?
A. No.
Q. And do you know what I mean when I say "explant"?
A. Yeah, sure. Somebody who's removed it, like a surgical specimen. No.
Q. Have you ever inspected polypropylene or a mesh explant of any kind?
A. No.
Q. Have you ever looked at explanted mesh under a microscope?
A. No.
Q. Is it correct to say that you've never been involved in a clinical trial to evaluate the safety or efficacy of a medical device or part or all of a

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device that was either polypropylene or synthetic surgical mesh?
A. Correct.
Q. And you did no mechanical testing of the mesh in Prolift+M?
A. Correct.
Q. You did not do any type of testing or measurements on the mesh in Prolift+M?
A. Correct.
Q. And that's not something you would do in your normal practice?
A. Correct.
Q. Have you ever diagnosed pelvic organ prolapse?
A. Well, yes.
Q. When was that?
A. When I used to do OB/G -- and when I did GYN exams.
Q. When was that?
A. That would be in the '80s. I mean, I had a clinic, and so we would see women all the time for GYN clinic day. So, yeah, I've seen prolapse.
Q. Did you ever treat it?
A. Not with mesh or surgically treat it, no. If a woman had problems, then you would send her to

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a urologist at that time. That was in the '80s.
Q. Did you ever perform any surgery to treat pelvic organ prolapse?
A. No.
Q. Do you believe that today you have the requisite education, training, and experience to counsel a patient about the treatment options for pelvic organ prolapse?
A. I wouldn't engage in that. I'm a regulatory expert. I'm not going to consult with patients about it.
Q. Have you ever implanted a medical device used to treat pelvic organ prolapse?
A. No. We used to use pessaries and things for that, and -- but that was not implanted.
Q. Do you consider yourself an expert in pelvic organ prolapse?
A. No.
Q. Have you ever implanted or explanted any medical device?
A. I don't know. I mean, it wouldn't have been a major -- I mean, there's some devices that are small that you would have implanted or -- I don't know. I mean, it's a long time ago.
Q. When was the first time you heard of Prolift

or Prolift+M?
A. When I was asked to look at it.
Q. In litigation?
A. Yes, sir.
Q. Any idea as to how many Prolift+M devices have been implanted in the United States or in the world?
A. No, sir.
Q. Have you ever seen a Prolift or Prolift+M implanted in the body in a live setting?
A. No.
Q. Have you ever watched a video of a Prolift or Prolift+M procedure?
A. No.
Q. Have you ever held a Prolift or Prolift+M device in your hand?
A. No.
Q. Have you ever been in the same room with a Prolift or Prolift+M device?
A. No. Nobody at the FDA would be either.
MR. AYLSTOCK: Whenever you get to a breaking point, my coffee is out.
MR. GAGE: That's fine. Why don't we stop. Yeah, let's take a quick one here.
(Short recess was taken.)

BY MR. GAGE:
Q. Dr. Parisian, would you agree that there are patients who have had Prolift+M implanted who have had no complications?
A. I don't know.
Q. Would you agree that there are patients who have had good experiences with Prolift+M?
A. I don't know. That would be the urologist and gynecologists talking about that.
Q. Would you agree that there are women who have a Prolift+M placed where it has been a safe and effective device for them?
A. I don't know.
Q. Would you agree that there are a significant number of doctors in the United States who believe the Prolift+M was safe and effective?
A. You know, I don't know, but I mean, the FDA is going to reclassify all these POP devices in order to have a PMA. So FDA doesn't agree with that, so I don't know.
And so you're asking me questions. Who knows? You have to have follow-up. So I don't know.
(Whereupon, Exhibit No. 12 was marked for identification.)

BY MR. GAGE:
Q. Dr. Parisian, I'm handing you just a chart of the pelvic anatomy that I've marked as Exhibit 12.
Are you familiar with the pelvic floor anatomy?
A. As a pathologist, yes, sir.
Q. Are you familiar with the POP-Q system?
A. The POP-Q system?
Q. Yes.
A. No.
Q. Do you know what that is?
A. I know what POP is, but I don't know what the Q part is.
Q. All right. So if I were to ask you to draw for me on this chart the various points, such as point AA, point BA, point C, point D, under the POP-Q system, would you be able to do that?
A. No.
Q. All right.
(Whereupon, Exhibit No. 13 was marked for identification.)
BY MR. GAGE:
Q. Dr. Parisian, I'm handing you Exhibit 13. Do you know what that is?

A. This is -- this is -- I don't know if it's Prolift+M or Prolift. This is the pelvic floor, what it looks like in the 510(k) in terms of the diagrams. I'm not sure which one it is particularly, but it would be the different pelvic floor mesh configurations with the arms like -- so that's what it is.
Q. Are you able to discern as between these three which is the Prolift total -- Prolift+M total, the Prolift+M anterior, and the Prolift+M posterior?
MR. JONES: Objection.
THE WITNESS: Well, my guess would be that the first one with all the stuff is the total. And I'm not -- I'm not sure which one would be the anterior and which would be the posterior.
I'm guessing. I mean, I'm not the person that would be doing this, but -- so I think the one that's got the biggest one here, that would be total.
BY MR. GAGE:
Q. All right.
A. Because it's got everything on it.
Q. And the one that you're pointing to is the one on the far left?
A. Yes, sir.

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Q. All right. Dr. Parisian, I read your Prolift+M report, and is it -- it's correct to say that you are critical of both the Prolift+M instructions for use and the Prolift+M patient brochure.
Is that a fair statement?
A. Oh, I think we start further back than that.
I think the design and the development of the product, the -- and the information being provided to the physicians from what the company knew in Europe.
So, yes, I am critical of that, but it starts back further than just the brochure and the IFU.
Q. Okay.
MR. GAGE: So move to strike as nonresponsive.
BY MR. GAGE:
Q. Just focusing in on the IFU and the patient brochure, is it correct to say that you are critical of the IFU and the patient brochure for Prolift+M?
A. Yes.
Q. Okay. Have you drafted an IFU or a patient brochure for Prolift+M that you believe is adequate?
A. No.

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Q. Have you provided -- or strike that.
Do you have a document that you have edited that would show edits or changes to the existing Prolift+M IFU or patient brochure that would, if adopted, make it adequate?
A. No.
Q. Do you intend to testify before a jury that the inclusion of specific words or the removal of specific words in either the IFU or the patient brochure would be necessary in order to make those documents adequate?
MR. JONES: Objection.
BY MR. GAGE:
Q. Do you understand what I'm saying?
I'm trying to understand whether you intend to testify to a jury, "Here's -- here's the list of the -- of the specific words that they should have included in an IFU in order for it to be adequate," or "Here's a list of the words that should have been taken out of the Prolift+M IFU in order to make it adequate."
MR. JONES: Objection.
THE WITNESS: I mean, a lot of it is going to depend on what the physicians say, what they think they should have known for their

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particular case. I mean, that's usually what has happened.
If a physician said, "I needed to know this, I needed to know that," then I'll look at the IFU and I'll say, "It's not there," the information that they were asking about.
And then the other thing that I usually testify to are the types of information that are specific to Prolift+M that are not in the label. And so I would give that.
But have I written a label, no, and it would usually be, "This is the types of information that a physician would need to know." Usually it's reinforced by what the physician says, and then it needs to be made specific for Prolift+M.
What are the things that you're having in the literature, the reports? What was it that they knew in France? I think I said about the 2D imaging, that you could look at the 2D imaging and see if the person was having the -- the product eroding.
So there are some things in my report as to things that would need to be in an adequate IFU, but I haven't written an adequate IFU for it.
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BY MR. GAGE:
Q. Have you ever spoken with a doctor who has implanted a Prolift or a Prolift+M device?
A. No.
Q. Have you read the depositions of any doctors who have implanted Prolift or Prolift+Ms?
A. No.
(Whereupon, Exhibit No. 14 was marked for identification.)
BY MR. GAGE:
Q. All right. Dr. Parisian, I'm going to hand you a chart I marked as Exhibit 14. I will confess to that I -- it's in my own handwriting, and I only have one copy which you and Nate can look at at the same time. And I may have to come around on your side of the table so I can kind of look at it.
But I want you to just take a look at it and I'll give you a second to read it.
A. Okay.
Q. So, Dr. Parisian, what I've got there is a circle divided into, I guess, eight piecharts -- or pie slices, and I've gotten -- I've written in that -- in those piecharts, IFU, Prof. Ed, which means professional education, then med school/training, then med lit, which means medical

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literature, then colleagues, then experience, then patient brochure, and then I think I wrote Surgeon's Resource Monograph.

Do you see that?

A. Yes, sir.

Q. Okay. Do you agree that -- and I think at the title, it says, "Sources of Risk Information." Is that correct?

A. That's what your title is.

Q. All right. Do you agree that -- well, first of all, you understand what professional education is?

A. Yes, sir.

Q. Okay. And, obviously, you know -- you are generally familiar with all the other components of that pie chart. Is that correct?

A. Yes, sir.

Q. Are you familiar --

A. Now, are you talking about just hypothetically in general?

Q. In general.

A. Because it doesn't really reflect what's happening with Prolift+M.

Q. That's correct.

A. Okay.

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Q. I'm just talking about in general.

A. Okay.

Q. Are you familiar with the Surgeon's Resource Monograph?

A. Right. That would be your training manual for the surgeon.

Q. Yes.

Did you -- is that one of the documents you reviewed?

A. I reviewed it, but I'm not a surgeon, but in terms of -- I mean, because one of the things missing here is your sales force, and that company is doing the training course.

And so this is -- this -- this diagram is more typical of traditional -- like a urologist practice or something.

But in terms of these cases where the -- the company is the one responsible for the procedure and the training and stuff, it doesn't really reflect the company's involvement.

Q. All right. So let's -- I take it we need to add the sales force to that chart?

A. I think it would be a big piece of pie on this and also their courses that they have, because your resource monograph is just the book, but

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they're going to, actually, training classes.

Q. Maybe you and I are missing each other a little bit.

A. Probably.

Q. I had referred -- when I was referring to Prof. Ed, I was referring to the Ethicon professional education, which would include everything that would fall underneath that umbrella, such as, you know, didactics, seminars, sales force interaction, and that sort of thing.

If I wrote "Ethicon" above "Prof. Ed," would that help fill out that piece of pie chart for you?

A. It would be better, but I think it would be much bigger, because in this particular case, the surgeon is actually dependent on the company to give them all the training and to develop the procedure.

Q. All right. So what I've done is I've written in "Ethicon" above "Prof. Ed." I think that would -- that cures at least some of your concern about the chart; correct?

A. If you're talking that's the cadaver lab, that's where they're training -- okay, all right.

MR. JONES: Sales reps --

THE WITNESS: Sales reps.

MR. JONES: -- sales reps, I think, is

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the --

THE WITNESS: Is missing.

MR. JONES: -- is the issue.

BY MR. GAGE:

Q. So we'll call it "Ethicon Prof. Ed," and what would be the words you would like to put in there? Sales reps? Sales training? How would you --

A. It would be a bigger piece of the pie because in this --

Q. I'm going to let you -- I'm going to ask you later to give me some -- I'm going to let you in a sense adjust the sizes of the piece of the pie in just a minute.

So I just want to get the pieces of the pie properly dominated at this point.

A. Well, let me see. Where would you -- I mean, you don't have sales reps there.

Q. I know. I had included sales -- in my mind, I included sales reps under "Prof. Ed."

MR. JONES: Under professional education?

I think in her mind maybe they're -- maybe that's the disconnect. Because she can help you fill out this chart, and that's what she's

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trying to do.
BY MR. GAGE:
Q. What words can I put into that Ethicon Prof. Ed that would encompass in your mind the totality of what's coming from the company in that section?
I'm not trying to trick --
MR. JONES: And don't feel constrained by his terms. You know, you're getting caught up on he's made them all equal spaces, so don't be confined with trying to fill in his charts the way he has done it.
THE WITNESS: Well, let me do it, because this -- this big piece of the pie is the -- is more the sales rep, because they're -- they go through the IFU. They go through the monograph with the doctor.
So they're the ones who -- this would all be sales reps would be doing this, because they make the thing for the people to go to courses. They're -- so they're all setting it up, selling this thing here.
BY MR. GAGE:
Q. Okay.
A. Okay. So that would be the sales rep. All of this stuff would be them.

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Q. All right. And just for the record, what you've done is you've written "sales reps" over "Surgeon's Resource Monograph, IFU, and Ethicon Prof. Ed"?
A. Right.
Q. Do you want to -- I've wrote the word "and."
Do we need to delete -- strike through the word "and"?
A. There we go. We get rid of that.
Q. Okay.
A. But, see, I look at this as this is a big part of the pie. The medical -- they're trained -- they're doctors, yes. Medical literature, when you learn these procedures, there's not a lot of medical literature. And in terms of the Prolift+M, most of that had been done in France.
Q. Okay. We'll get -- I'll get back to the specifics of each of the piecharts. I just wanted to understand what your view was of the -- of the pie chart.
Now, you're still --
A. Because the patient brochure comes from Ethicon too.
Q. Got it.
A. So we have to -- so that made it a bigger --

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a bigger piece. So you've now got the doctor involved with this thing that mainly comes from Ethicon. They don't know anything about it.
And so, yes, they are trained. They're a licensed doctor. The medical literature, there isn't really any. Colleagues, most of their colleagues don't know about a new thing either. So this is -- this is the big -- it's almost half the pie.
Q. All right. So -- and, again, you just -- the -- everything in red is your handwriting with the exception of where I wrote the word "Ethicon"; correct?
A. Yes, sir.
Q. And I think you've explained why you group those together, and sales reps run across those four pieces of the pie that you've marked in red?
A. Right.
Q. All right. Okay. Are there any other sources of risk information that you think is missing?
MR. JONES: Objection.
THE WITNESS: Sources of risk information?
Well, as -- as in my report, when I

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talk about -- if we're talking specifically about Prolift+M, the thing that's missing is a lot of the European data. That -- that is not being given to the physicians in terms of experience. So they're not getting the foreign experience in terms of the physicians having problems with the Prolift+M.
BY MR. GAGE:
Q. But I think that -- I think it would be your opinion, would it not, that that's something that Ethicon should be providing in either the Prof. Ed, the IFU, the Surgeon's Resource Monograph or the patient brochure; right?
A. It's my opinion they should, but they didn't.
And the Prolift -- the Prolift is where this all comes from, and that had been off label. That had been no real training, no real development.
So you have American physicians that are getting into the Prolift and, you know, they didn't -- they didn't have that -- that wealth of experience from France, and so experience is one thing, because I assume you're talking about the doctor's experience doing procedures?
Q. That's correct.
The sources of risk information that are

available to doctors.
A. Right, and that would be his medical experience, but I think the history of the use of the device outside the country, that was not being given to the doctors. It wasn't given to the FDA either.
So, you know, this experience part here is -- you know, you're talking about their experience, so this would be --
Q. I'm talking about the surgeon --
A. Right.
Q. -- the individual surgeon's experience.
A. Right. Right here. He's --
MR. JONES: Experience with -- sorry. Experience with what?
THE WITNESS: Yeah.
Surgeon experience because most of these surgeons don't have any experience with this stuff, and there's a huge learning curve.
So this would be your French data, European data, the learning curve, learning curve. The other thing is that only 10 to 20 percent of the physicians were being asked, and they were all very experienced.
So you have no surgeon experience,

which is a whole other horse of a different color. The colleagues -- you know, Ethicon actually has some input, what their colleagues are telling them, so we don't know what -- Ethicon's input to that.
So, I mean, that's why you have to divide the experience as to what actually happened with the device, that only 10 to 20 percent were being trained how to use it. They were having significant learning curves.
So now if you talk about a new surgeon experience, he may not have had it. He didn't have any experience.
BY MR. GAGE:
Q. Could a surgeon gather any -- could a surgeon implant, for example, another manufacturer's device and have any of that experience carry over to the understanding of the risks of Prolift+M?
A. In terms of the 10 to 20 percent that they selected, the company, to train in Europe, those people had experience with other devices.
Q. Well, I'm just talking about in general.
If a surgeon, for example, had implanted 1,000 pelvic meshes before that were not Prolift+M but then implanted a Prolift+M, would there be any translatable experience?

MR. JONES: Objection.
THE WITNESS: You know, I would leave that to a surgeon to explain that, but I know that in terms of Europe, the surgeons that they had used were very experienced, and they had difficulty with the product, and there was a huge learning curve.
And I know when they went to marketing in the United States, they were looking for surgeons who did not have experience, who had not wanted to use mesh.
So they were targeting doctors who weren't necessarily that experienced in it, so that's why the pie kind of changes because experience, they're not giving the surgical experience in the vast, and I think that that was what was big about the Prolift+M.
BY MR. GAGE:
Q. Are you aware that some doctors do not read the IFUs or patient brochures before implanting surgical mesh?
MR. JONES: Objection.
THE WITNESS: You know, in terms of the surgical field, oftentimes the IFU is implanted sterile, and so if you ask --
///

BY MR. GAGE:
Q. You said the IFU is implanted sterile?
A. Well, it is sterile. It's in the sterile package. And so they're not going to sit in an OR and read it.
They tend to read it outside of the OR, so some doctors will say, yeah, I didn't read the IFU in the OR because it costs money to sit there and read the IFU.
You already decide you're going to use it, so they may have read marketing at some point in time, but the IFU still was required to be adequate instructions and warnings by the regulations whenever they read it.
Q. Do all doctors read the IFUs?
A. You know --
MR. AYLSTOCK: Objection.
THE WITNESS: -- I can't answer for all IFUs. I just can answer what is required of an IFU.
BY MR. GAGE:
Q. All right. Let me ask, is it acceptable medical practice for a pelvic floor surgeon to implant a Prolift+M without first reading the IFU?
A. It depends. It depends in what they've been

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told, if they've gone to training courses. It depends, you know, to say that they've obviously had some training, so each case is going to have a surgeon that's going to answer that question.

Q. All right. So if a surgeon testified in a particular case that he or she did not read the IFU, that wouldn't necessarily trouble you?

MR. JONES: Objection.

MR. AYLSTOCK: Objection to form.

THE WITNESS: Oftentimes -- not necessarily because oftentimes they will be talking about an IFU that was in the surgery. You're not going to read it there. And then oftentimes you back them up, and you go, "Well, did you go to a course? Did you rely on the sales reps?"

So it's -- the other things are important besides the IFU. The sales rep is a huge entity in terms of this product. The training courses they go to.

So just -- I'm not going to fault somebody for not regarding the IFU because usually they're inadequate anyway, the way they're written. They're not writing robust IFUs.

But each surgeon is going to answer how they learned how to do this -- this course, but --

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so, I mean, in terms of medical implanted devices that the IFU has not looked at is not going to necessarily surprise me in the OR.

BY MR. GAGE:

Q. Have you conducted any study or survey of pelvic floor surgeons to determine whether they read the Prolift+M IFU?

A. No.

Q. Have you conducted any survey or study of pelvic floor surgeons to determine what risks they understood as a result of reading the Prolift+M IFU?

A. Well, I think the Prolift+M IFU is inadequate to begin with.

Q. I know.

But my specific question is, have you surveyed pelvic floor surgeons to determine what risks they understood as a result of reading the Prolift+M IFU?

A. No.

Q. Okay. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks of the device they understood as a result of medical school education?

A. No, I haven't done that.

Q. Could doctors have learned of the risks of

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Prolift+M from their surgical training?

MR. JONES: Objection.

THE WITNESS: No, I don't think so, because these -- these actually came out as procedure kits, and so that wouldn't have been in their medical training.

BY MR. GAGE:

Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks of the device they understood as a result of their medical school education?

A. No.

Q. What is the role, if any, of medical literature with regard to devices such as the Prolift+M insofar as the pelvic floor surgeons who might implant the device?

MR. JONES: Objection.

THE WITNESS: The role of medical literature is to impart some knowledge about -- about a particular -- I mean, what is literature in general? I mean, it's to tell you something.

But is that where doctors get information about devices? Not always. Usually there's a delay in what comes out in the literature compared to what is being done. It's usually about

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five years that you would think about a delay.

BY MR. GAGE:

Q. Should pelvic floor surgeons implanting Prolift+M read the medical literature about the device before implanting it?

A. You know, it's going to be up to the surgeon to talk about it. I can't -- I mean, I'm not going to say a surgeon has to read the medical literature, because for one thing I just said, there's usually a delay. When you introduce new technology, there may not be medical literature.

Q. If there is literature, should they read it?

A. It depends. I don't know. It depends on the surgeon, what -- how they learn stuff. What they're -- what they're doing.

I mean, in terms of a surgical practice, the surgeons don't always have time to read, to go look for the medical literature. Remember, now we've got the Internet, and it wasn't always that easy to find literature.

Q. Could doctors have learned of the risks of Prolift+M from their reading of medical literature?

A. Probably not.

Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to

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determine what risks of the device they understood as a result of reading relevant medical literature?
A. No.
Q. Could doctors have learned of the risks of Prolift+M from their experience implanting other mesh devices?
MR. JONES: Objection.
THE WITNESS: It depends. I can't give an answer on that.
BY MR. GAGE:
Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks of the device they understood as a result of their experience implanting other mesh devices?
A. No.
Q. Should doctors have availed themselves of training courses before they implant Prolift+M?
MR. JONES: Objection.
THE WITNESS: Again, each doctor is going to talk about that. I mean, yes, ideally, but I don't know what their experience is, so I don't know.
BY MR. GAGE:
Q. Could doctors have learned of the risks of

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Prolift+M from mesh device training courses?
A. Probably not since the company wasn't actually giving the information about the potential risks. They weren't updating the physicians as to the risks.
Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks they understood as a result of participating in training on Prolift+M?
A. No.
Q. Could doctors have learned of the risks of Prolift+M from Ethicon sponsored surgical training?
A. Based on the information I reviewed, no.
Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks they understood as a result of participating in Ethicon sponsored training on Prolift+M?
A. No.
Q. Should pelvic floor surgeons implanting Prolift+M read the patient brochure before implanting the device?
A. Not necessarily the patient brochure. I mean, the patient brochure is usually what they give out. I mean, it would be -- not be bad for them,

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but I don't think reading the patient brochure is going to tell you how to implant the product.
Q. Would it tell you anything about the risks of implanting the device?
A. Not the patient brochures I reviewed. Most of them, they were all benefits; no risk.
Q. Did you review the Prolift+M patient brochure?
A. I don't recall if I did or not in terms of I don't remember right now. But since the company wasn't collecting the long-term data, there's -- it's very unlikely there would be any information in it.
Q. Have you conducted any study or survey of pelvic floor surgeons who implanted Prolift+M to determine what risks of the device they understood as a result of reading the Prolift+M patient brochure?
A. No.
Q. And, Dr. Parisian, we talked earlier about the Surgeon's Resource Monograph.
A. The training manual, yes, sir.
Q. And forgive me, my memory is not as good as it once was.
Did you or did you not read it? I'm not

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trying to ask the same question twice. I just can't remember what your answer was.
A. I may have looked at it. Since I'm not a surgeon, I wouldn't have looked at it with great depth.
Q. Do you know if you -- do you know if it was a document that was provided to you?
A. I don't recall as we sit here today.
(Whereupon, Exhibit No. 15 was marked for identification.)
MR. GAGE: Okay. Doctor, I'm going to mark as Exhibit No. 15 a document, it begins with ETH.MESH 00658362. It's entitled the "Surgeon's Resource Monograph."
And before I hand it to you, I want to let counsel know that I received an e-mail a couple -- a day or two, yesterday I guess, from somebody in my office that said the copy I'm about to mark is missing a few pages at the end. And I had already left and didn't have time to get a better copy.
So I'm not going to ask Dr. Parisian about the specifics. I recognize I'm missing a few pages here, but I would ask permission of counsel for me to substitute the correct copy.

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I don't think it's -- I don't think the fact that there's some pages missing at the end are going to impact at all my questioning of the witness.

MR. AYLSTOCK: Yeah. Can you just identify which pages or --

MR. GAGE: I don't know. He just meant me -- my guy in my office sent me an e-mail and said, "Hey, I want you to know, that is the correct document, but I looked at it, and, apparently, we've got one -- there apparently are a couple pages missing near the end."

And I had already made copies and flown out here, so my request would be that we substitute the complete and full copy. I'm not going to ask the witness about the specifics of it such that the missing pages would impact.

MR. JONES: Sure. I mean, do you have a copy?

MR. GAGE: Yeah. And so there's a copy for the witness, and there's a copy for counsel, obviously.

BY MR. GAGE:

Q. Dr. Parisian, I just want to know, is this a document that is familiar to you, recognizing that I

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have been told that some pages are missing, a couple -- at least a couple of pages are missing near the end?

A. I don't -- I don't recall. I've looked at -- I don't recall.

Q. Does it look --

A. What's the date of this one anyway? This is -- I can't read the --

Q. I don't have a specific date for you. It's --

A. I can't read the -- all right.

MR. AYLSTOCK: It's sort of -- the copy is not very good.

MR. GAGE: Is there a copy review date at the back?

MR. AYLSTOCK: There's something, but it's very faint. I don't know.

THE WITNESS: So what's your question?

BY MR. GAGE:

Q. Well, my question is, is this document familiar to you?

A. I don't remember.

Q. And if it's not on your reliance list, is it -- is it correct to say that you've never seen it?

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A. Probably so if it's not on my list.

Q. All right. So, Doctor, I'm going to ask you a question, but if you have not seen the document, I don't believe you're going to be able to answer the question, but I'll ask it just to make sure.

Could doctors -- could doctors have learned of the risks of Prolift+M from reading the Surgeon's Resource Monograph?

And I suspect your answer will be -- well, let me strike that. Let me just -- let me re-ask it.

MR. AYLSTOCK: Okay.

BY MR. GAGE:

Q. Doctor, could doctors have learned of the risks of Prolift+M from reading the Surgeon's Resource Monograph?

MR. AYLSTOCK: And just for the record, there's no date here, and it's Prolift -- it's not the Prolift+M -- document just so the record is clear.

THE WITNESS: Right. So this is Prolift.

Well, it has a lot of questions because we don't know when a person took a course. We don't know what this one is. And it's Prolift, as opposed

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to Prolift+M. And there's nothing about postmarket, these are the rates that we have.

BY MR. GAGE:

Q. I'll tell you what. I will withdraw the question because the witness has not reviewed --

A. Thank you.

Q. Doctor, just to summarize, that document is not familiar to you as you sit here today?

A. Correct.

Q. And it is correct to say that if that document does not appear on your reliance list which we've marked as an exhibit, then it would be a true statement that today is the first day you've seen that document?

A. Yes, sir.

Q. Okay.

THE WITNESS: May I go to the bathroom really quick?

MR. GAGE: Absolutely.

THE WITNESS: All right. Be right back.

(Recess taken.)

(Whereupon, Exhibit No. 16 was marked for identification.)

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BY MR. GAGE:
Q. Dr. Parisian, I'm going to hand you a composite Exhibit 16, which contains, as I counted, 11 different pieces of medical literature regarding Prolift+M.
Could you just spend a few seconds looking through that and just generally familiarizing yourself with those documents?
A. Okay.
Q. Dr. Parisian, my question -- well, I'll make a statement, and then I'll ask a question.
I will represent to you that I had someone in my office look over your reliance list, and I've been advised by someone in my office that these pieces of medical literature regarding Prolift+M do not appear on your reliance list.
And my question to you is, are any of those pieces of medical literature familiar to you?
MR. JONES: Objection. I don't think that's a completely accurate characterization, but it's just an objection for the record.
MR. GAGE: It may not be. I was told they couldn't find them on there, and so I didn't go back and double-check, but I asked them to double-check, but I could be --

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MR. JONES: I think it just has to do with the data and then how it gets published, and I would say a lot of the underlying data is discussed actually in the body of the report and in these articles.
THE WITNESS: Some of them are, like I know the Taiwan study looking at the mesh versus the web, so some of them are but not all of them.
BY MR. GAGE:
Q. Do you know why -- assuming I'm correct about this, do you know why they would not be -- those that are familiar to you would not be specifically listed on your reliance list?
MR. JONES: Objection.
THE WITNESS: It's because I've looked at a lot of different mesh studies, and so I -- from a lot of different companies, so I might have seen them.
I'm not the person who's doing like the ultimate literature search and the -- I'm looking at it from what would have been known and knowable and information but not the person who is an expert in urological treatment of prolapse.
BY MR. GAGE:
Q. Who is doing the literature searches?

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A. I don't know.
Q. I'm talking about for you.
A. For me?
Q. Yes.
A. I do my own literature searches. What do you mean? In terms of --
Q. I'm sorry. I misunderstood.
I thought you just said a few minutes ago or just a second ago something that would suggest that you had someone else doing --
A. No.
Q. -- the literature searches for you.
A. No, no, no, no, because, I mean, I've looked at all kinds of mesh.
And so if I look at this document, would there be some things that I've seen before, and yes, I have. Did I do an ultimate literature search in my report for Prolift+M? No, I didn't do that. I don't even list that. But, you know, there are some articles I've seen, some articles I haven't seen.
Q. All right. Let me ask you this: Did you read any of the articles in Exhibit 16 for purposes of drafting your Prolift+M report?
MR. JONES: Objection.
THE WITNESS: I don't recall that I

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did, but some of those are things that I've seen, so I don't think so, and I don't think I referenced them particularly, but they're in my head in that I've seen these articles before.
BY MR. GAGE:
Q. Okay.
A. Does that answer your question?
Q. Yes. I think -- and I don't want to be unfair to you, so listen carefully.
I think what you're telling me is it's possible that you have seen one or more of these articles in Exhibit 16 through the course of your time working as an expert in the mesh litigation?
A. Right.
Q. But for purposes of drafting your Prolift+M report, you did not specifically review these articles for purposes of drafting that report?
A. Right.
And if you notice in my Prolift+M, there's no section that says the medical literature for Prolift+M.
Q. Why is that?
A. Because I didn't do that, and sometimes -- some reports that I do, but in this particular case -- I mean, it actually had a very short

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lifespan, and I focused more in my report on the 510(k) and the marketing information because we had the Prolift and the Prolift+M, so you're actually having two products in the one report.

Q. Is there some specific reason why you did not include a section in your report about the published medical literature on Prolift+M?

A. I just didn't do it. I mean, some reports I do. I didn't do it on TVT-Secur either, but sometimes I would, and then I would list them, but I didn't list them.

Q. Was that your decision?

A. It wasn't anybody's conscious decision. It's just not in the report.

Q. I see.

It wasn't that you made a conscious decision not to do it; it's simply that you didn't make a conscious decision to do it?

A. That's right. Because I felt like there were more people who were talking about the urology, the treatment of patients, and I didn't see that as my role.

Q. Dr. Parisian, you are aware that there are various surgical procedures to repair pelvic organ prolapse that don't involve the use of mesh;

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correct?

A. Right. Those are your traditional ones for the urology group.

Q. Do you know what the risks of those non-mesh pelvic organ prolapse surgeries are?

A. No, not offhand.

Q. I'll ask you some and then -- I'll ask you about some of the risks, and I'll ask you to let me know whether you believe it's a risk or not.

So the first question is, is pain with intercourse a potential risk of a non-mesh pelvic organ prolapse surgery?

A. It can be, but when are you talking about the pain? Dyspareunia, that would be -- because typically when you think of dyspareunia in those patients, it's usually acute. It's not something that's chronic.

In our cases, the women -- and I'm not going to be talking about this in terms of the symptoms, I don't believe. Am I?

But in terms of dyspareunia, the thing that was unusual here is that it's chronic, it's prolonged, and it can be dyspareunia for a woman and also for her partner in that they can actually feel the mesh.

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Q. Is chronic dyspareunia a risk of a non-mesh surgery to POP?

A. I don't know that it --

Q. POP -- when I say "POP," you understand what I mean, pelvic organ prolapse, P-O-P?

A. Yeah, pelvic organ prolapse.

Q. Okay. So let me rephrase the question.

Is chronic dyspareunia a risk of a non-mesh surgery to treat POP?

MR. JONES: Objection.

THE WITNESS: And I would say I don't know. Because when they used to do non-risk -- non-mesh surgery, those patients were usually chronic patients to begin with. They didn't -- what's new is that we have the -- the POP procedures with the mesh being done on women who were healthy and had no problems.

So that you have to look at the pre-transvaginal mesh surgery as these are patients who are chronic that went to surgery, so I don't know.

So, again, it would be a urologist talking about that, but this would be, for our transvaginal mesh, could have chronic dyspareunia in a woman that was -- didn't have it to begin with,

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whereas they may have had it with the other surgery.

BY MR. GAGE:

Q. What we would call de novo dyspareunia?

A. Yeah.

Q. Okay. Is de novo chronic dyspareunia a risk of a non-mesh surgery to treat POP?

A. I don't know because I'm saying with the caveat that those patients who got treated surgically before, like with the Burch or Marchetti, those types of procedures, they -- they actually had a whole bunch of symptoms before their procedure. So I don't know if it was -- de novo was new for those procedures.

Q. Is chronic dyspareunia a risk of a Prolift+M surgery?

A. Yeah.

Q. Is -- does the fact that Prolift+M carries with it the risk of chronic dyspareunia mean that the device is defectively designed?

A. You know, I don't think I've seen a good reason for what the dyspareunia is coming from, so I think that would be others who would talk about that.

Q. All right.

A. Because you could have dyspareunia for many

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different factors, so it could be the overall design, surgical. I don't think that's necessarily what I'm talking about in terms of litigation.
Q. Is chronic pain a general risk of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: Well, you know, I'm going to fall back on the FDA saying that they were looking at the non-TVM risks, and they were saying that the risks were unique compared to the risks for the surgical procedures.
So the FDA has made that the risks are unique and different for these TVM procedures compared to the traditional surgical procedures.
And that's actually what they're going to be doing the PMAs for, to find out that answer, so I can't answer it. That's what the FDA is trying to get data for.
BY MR. GAGE:
Q. So my question -- I think my question is, is chronic pain a risk of a non-mesh surgery to treat pelvic organ prolapse?
That's my simple question.
MR. JONES: Objection.
THE WITNESS: And I would say I don't

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know, and there's going to be more information -- that's what the FDA wants to know. Was chronic pain for the traditional surgical procedure, is it worse now for the TVM procedures? They're trying to quantify that.
BY MR. GAGE:
Q. Is vaginal scarring a risk of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: I don't -- I don't know. And vaginal scarring I don't think was -- but, again, this would be a different -- this is apple and oranges in terms of the patient, so I don't know.
BY MR. GAGE:
Q. Is injection a risk of a non-mesh surgery to treat pelvic organ prolapse?
A. Infection is a risk for any kind of surgery, but the issue is that the mesh makes it much more difficult to treat the infection.
Q. Are urinary problems, including urinary frequency, retention, obstruction, urge incontinence, and voiding dysfunction a risk of a non-mesh surgery to treat pelvic organ prolapse?
A. I don't know. In terms of who the woman is,

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what the procedure is, I can't answer that. That's what the FDA is trying to get them to answer.
Q. Is organ or nerve damage a risk of a non-mesh surgery to treat pelvic organ prolapse?
A. It can be.
Q. Is bleeding a risk of a non-mesh surgery to treat pelvic organ prolapse?
A. Well, bleeding is always a risk of a surgery. The question is not is it a risk. The issue is, is it worse? For a woman that was fairly stable to begin with is it worse than would be anticipated if she had gone with a traditional procedure?
So you're talking apples and oranges. The traditional procedures were people who were in bad states to begin with.
Q. I understand that. I'm not really doing the comparison right now. I'm just simply asking whether these risks are risks of non-mesh surgeries to treat pelvic organ prolapse.
I have not yet gone to the next question about comparing those non-mesh surgeries to mesh surgeries.
A. Okay.
Q. So are wound complications a risk of a

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non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: Yes. It can be. A wound complication, yes.
BY MR. GAGE:
Q. Is inflammation a risk of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: It can be. Any surgery can have inflammation risks.
BY MR. GAGE:
Q. Is fistula formation a risk of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: It can be.
BY MR. GAGE:
Q. Are neuromuscular problems a risk of a non-mesh surgery to treat pelvic organ prolapse?
A. It can be.
Q. Is there a risk that one or more surgeries may be needed to treat an adverse event arising out of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: Yes.

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BY MR. GAGE:
Q. Is a manufacturer of a surgically implanted medical device required to warn surgeons of the general risks of surgery or of only those specific and unique to the device itself?
A. Both.
They're supposed to provide adequate instructions and adequate warnings. So there can be general surgical risks, yes, but you have to make the -- the information so that the physician would know, in terms of your device, what are the potential risks and benefits so they can make an informed decision.
Q. If a risk is common to both a mesh surgery and a non-mesh surgery, must -- must the manufacturer of a medical device making that mesh include that risk in the IFU or the patient brochure?
A. Yes, because as I've been trying to say, there's two different populations. The woman who went through the traditional, non-mesh surgery was a different population than this woman that would have a 15-minute office procedure, and they usually had minor symptoms.
So in terms of the risk versus benefit, a

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woman who's had a bad outcome and problems would be able to accept different risk versus benefit than a woman who has really insignificant issues.
And so you have to as a manufacturer give adequate information to the doctor to make a risk versus benefit determination.
You're taking a woman that's almost healthy and giving her an elective procedure. The benefits are not that great, so your risks have to be commiserate with that type of a procedure.
So, yes, the manufacturer is required to provide that literature in their label.
Q. And just so that we're clear, that information -- when you use the phrase "that information," you include within that not only the risks that are unique to mesh devices, such as the risk of erosion, but also every risk that could potentially occur even if that risk was not unique to that particular device?
MR. JONES: Objection.
THE WITNESS: What you've forgotten is that you got to put the risk for your device in there. You haven't said that. You said that we would have, you know, general risks that -- for surgery, yes, okay.

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But you, as the manufacturer Ethicon, have to have a postmarket surveillance group that's determining what your risks are specific for your device to put in your label.
And so that's what's missing is, yes, there are some generic terms that people have put in for mesh, but what's missing from the label is, how does Prolift work in terms of a patient? How does Prolift+M work in terms of a patient? A physician can decide whether to implant it.
BY MR. GAGE:
Q. Is foreign body response a risk of a non-mesh surgery to treat pelvic organ prolapse?
MR. JONES: Objection.
THE WITNESS: You can have foreign body response -- I mean, it's a very generic name, so what are you talking about, "foreign body response"?
BY MR. GAGE:
Q. Do you know what foreign body response is?
A. Sure, I know what it is, but what do you want? Because a foreign body response, you can have -- like a suture can cause a foreign body response. And a lot of times sutures will get expelled. That's a foreign body response. Or you can have the mesh, which is a foreign body, causing

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it. So what foreign body response are we talking about?
Q. Well, I think my question was, is foreign body response a risk of a non-mesh surgery that uses any foreign body to treat pelvic organ prolapse?
A. It can be, but the company has to provide a description. What's the likelihood of having a foreign body response with Prolift+M?
I mean, we're talking about Prolift+M. That information needs to be in the label. So you don't say it's minor. How big of a foreign body response are we talking about?
Q. Are surgeons taught about foreign body response in medical school?
MR. JONES: Objection.
THE WITNESS: In a generic fashion, yeah. Foreign body response is a known term that surgeons would know about. The thing is --
BY MR. GAGE:
Q. What are they taught?
A. What are they taught? I mean, I think if you're talking about most surgeons, I mean, a foreign body response would mean there's a risk of -- that's why a lot of surgeons don't want to put any foreign materials in a human because people will

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respond to the foreign materials.
But the question is the degree of foreign body response that we would have for Prolift+M.
Q. All right. And my question is, what are surgeons taught?
MR. JONES: Objection.
THE WITNESS: Well, I mean, I can't talk for all surgeons, but I know that for foreign body response is -- from a surgeon's point of view, it's a foreign body. So suture can cause it. Anything that's a foreign body can cause a foreign body response.
BY MR. GAGE:
Q. How long can that foreign body response persist?
MR. JONES: Objection.
THE WITNESS: It depends on the foreign body response. It can persist. Like if you leave a sponge in somebody, that will create a foreign body response and eventually will manifest with an infection or something that might trigger it to come out.
So it's just -- it's a big spectrum, foreign body response, so I don't think I can answer it any other way.

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BY MR. GAGE:
Q. But is that something that's taught to surgeons in medical school or during their training?
MR. JONES: Objection.
THE WITNESS: You know, we're talking about the degrees. I mean, because pathologists, we're sitting there describing foreign body responses, and so we are very meticulous. We look at it, whether it's chronic, whether it's acute, you know, the cell type, and all that stuff.
Surgeons just tend to think it's a foreign body, you can have a foreign body response. So there's all kinds of gradations of foreign body response.
So, yeah, I think everybody who goes to medical school knows you can have a foreign body response, but you need to tell them what kind of foreign body response you're going to have, and is it going to be severe foreign body response?
So it's the two words, foreign body response -- three words, yes, they know those words. But you have to -- as in adequate instructions and warnings, you have to tell them what is to be anticipated for this product.
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BY MR. GAGE:
Q. Was the risk of chronic dyspareunia with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: I don't -- I think that the medical community's going to have to talk about it in terms of the FDA didn't make it sound like they were in terms of their public health notification.
BY MR. GAGE:
Q. Well, I'm --
A. I mean, chronic dyspareunia is -- chronic dyspareunia is a significant problem with a device.
Q. Dr. Parisian, I'm very specific, just asking you this question: Was chronic dyspareunia with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: I don't know. I can't talk for every -- I mean, again, it would be the physician that's caring for the patient.
BY MR. GAGE:
Q. Was the risk of chronic pain with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: I can't speak for what

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the medical community knows.
BY MR. GAGE:
Q. Was the risk of vaginal scarring with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: You know, I can't speak for the whole medical community. I don't think so.
BY MR. GAGE:
Q. Was the risk of urinary problems with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: Well, you're talking about general. You're not talking about Prolift+M?
BY MR. GAGE:
Q. Correct.
A. You're just talking general. I don't know.
Q. Was the risk of organ and nerve damage with mesh devices known to the medical community in 2008?
A. I don't know.
Q. Was the risk of bleeding and wound complications with mesh devices known to the medical community in 2008?
A. Again, I can't answer that. I mean, these are complications of surgery, but whether an individual surgeon who was putting this in knew

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that, I can't answer that.
Q. Was the risk of inflammation with mesh devices known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: I can't answer it.
BY MR. GAGE:
Q. Was the risk of fistula formation known to the medical community -- I'm sorry. Strike that.
Was the risk of fistula formation with mesh devices known to the medical community in 2008?
A. I don't -- I don't know if it was or not, and that was part of the issue that the FDA came out with that public health notification is that they were concerned that people weren't aware of the risks.
Q. Was the risk of neuromuscular problems with mesh devices known to the medical community in 2008?
MR. JONES: Same objection.
THE WITNESS: I don't know. Same answer.
BY MR. GAGE:
Q. Was the risk that a surgery involving a mesh device might necessitate one or more surgeries to treat an adverse event known to the medical community in 2008?

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MR. JONES: Objection.
THE WITNESS: I don't think so, and I can't answer for the medical community. That was why the FDA was asking for that information.
BY MR. GAGE:
Q. Was the risk of erosion, exposure, extrusion with mesh devices known to the medical community in 2008?
A. Again, I can't answer that.
Q. Was the risk of contraction or shrinkage of the mesh known to the medical community in 2008?
MR. JONES: Objection.
THE WITNESS: Same answer.
BY MR. GAGE:
Q. Dr. Parisian, with regard -- let me -- well, strike that.
(Whereupon, Exhibit No. 17 was marked for identification.)
BY MR. GAGE:
Q. Dr. Parisian, I'm going to hand you Exhibit 17. Do you know what that is?
A. It looks like the labeling for the Prolift+M.
Q. And I've often referred to it as the IFU, instructions for use.

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Is that what your understanding is?
A. Yeah. Yes, sir.
Q. You don't need to call me "sir."
Have you reviewed this document in preparation for your report?
A. I don't -- I don't recall that I have.
Q. Do you recall whether you looked at the Prolift+M patient brochure?
A. I don't recall what I looked at as we sit here.
Q. All right. I just got a few questions about the -- about the IFU.
Can you see on the second page, about four lines down, it says, "The safety" -- do you see the paragraph beginning with, "The safety and effectiveness"? Do you see that?
A. Where are you? Oh, okay. Yes, sir.
Q. Okay. So I'm going to read just a sentence there and ask you a question about it.
It says, "The safety and effectiveness of the Gynecare Prolift+M systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized clinical trials."
Do you see that?

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A. Yes, sir.
Q. What does that communicate to a surgeon who reads that sentence?
A. That there haven't been -- this is something FDA requested, that there haven't been clinical trials for -- to look at the Prolift+M system.
Q. All right. And then two -- skip a sentence, and let's go to the next sentence that reads, "Information on." Do you see that, in the same paragraph? Actually, it's the next to last sentence in that paragraph.
A. Yes.
This is -- this is -- I remember this. This is the -- the thing that the FDA and the company debated on. The FDA just wanted it to be that first line all along about there had been no randomized control or trials, and then they negotiated at the last minute that they would have this information. You skipped the part about the bench testing and cadaver testing.
Q. Yes.
A. And the company asked for that, that they wanted to have that there's -- so that implies that there actually has been some testing, which isn't what the FDA had wanted.

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And then they have, "The information is available in the public literature." The FDA wanted them to put in some references to certain articles, and they said that -- Ethicon said we wanted to put in that we want you to contact our company sales representative for assistance.

So this was -- this is discussed in my report is that negotiated statement that was between FDA and the company.

Q. Is it a good thing that the -- that the first sentence appears in the IFU?

A. Yeah. That was the line the FDA asked for, because they -- they were concerned.

Q. Do you agree that it should have been included?

A. Yeah. I think it should have been included all by itself and not the other stuff that they put in about the cadaver testing and the bench testing.

That was what the company threw in. I think it would have been much more robust just to have that one line that there's no -- there's no data. There was no data supposedly for this product, which is what FDA was trying to give the physician.

Q. All right. So the sentence -- you see the sentence beginning with, "Information on"?

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A. Yes, sir.

Q. Okay. It says, "Information on the clinical performance of mesh for pelvic organ repair is available in published literature."

Do you see that?

A. Yes, sir.

Q. What does that communicate to a surgeon who is reading that sentence?

A. It sounds like there's actually clinical performance information about this device, and that's not true, and then contact your sales representative.

The first line is the important line. There's been no study. And so then when you start getting down in this statement where there's been bench testing and cadaver testing, there really hadn't been, and then the information, go talk to your sales rep, so that's basically a sales promotional-type thing. And this was negotiated at the last minute with the FDA.

Q. Is it -- okay. So the sentence that says, "Information on the clinical performance of mesh for pelvic floor repair," is that a true statement?

I'm sorry. Let me strike that.

"Information on the clinical performance of mesh for pelvic floor repair is available in published literature," is that a true statement?

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A. Yeah, but it really has nothing to do with Prolift+M, so it watered down what FDA was asking for, a statement that there is no information on this stuff, surgeon, so surgeon beware.

And instead the company put a much more user-friendly statement in there because the mesh has nothing to do with Prolift+M. I mean, there's a lot of mesh literature but nothing about Prolift+M.

Q. Is it your opinion that the -- that the entirety of the mesh literature that preceded Prolift+M is not relevant to Prolift+M?

MR. JONES: Objection.

THE WITNESS: Not for a surgeon. I mean, the surgeon is trying to figure out, should I use this versus somebody else's thing? Should I use the traditional?

So in terms of this information, it's misleading. It's making it sound like there is no information, but we have mesh information that you can look at, so you've watered it down.

And so it's unfortunate, and I talk about it in terms of the negotiation. It watered it down and made it a much more marketing friendly

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statement to say there's no information. The other mesh literature has nothing to do with Prolift+M, and so it's misleading to even put it there.

BY MR. GAGE:

Q. What about the literature on Prolift? Would it have any relevance?

A. Not necessarily because this is Prolift+M, and FDA said they wanted the two to be clearly separate in terms of information.

Q. Let me ask you this: When a device manufacturer submits a 510(k) to the FDA for a device, is it inappropriate for the company to point to medical literature that relates to a product or device?

A. No, but Prolift is not the predicate. I mean the --

Q. That wasn't my question.

A. No.

Q. My question doesn't have anything to do with Prolift or Prolift+M.

When a device manufacturer submits a 510(k) --

A. Right.

Q. -- to the FDA, is it ever appropriate for the manufacturer to cite to medical literature that

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pertains to the predicate?
A. Yes.
Q. Why?
A. Because the reviewer has to have a background of the summary of the safety information. And if there's relevant information in the medical literature, that should be given to the FDA reviewer so they can consider whether they -- there are new issues of safety and effectiveness, if they need to ask for testing information.
And so, yeah, that makes -- that would be logical to give that to the FDA. In fact, you're required to do that in terms of no material fact not provided to the FDA.
Q. All right. But as I understand it, that same analysis is not appropriate in the context of an IFU for a medical device?
MR. JONES: Objection.
THE WITNESS: No, that's not what I'm saying.
In this particular case, the FDA had wanted that line that there was no information of Prolift+M, that it concerned the FDA. And then the company said, no, we're going to -- and they negotiated this other statement, which waters down

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the message, which is there is no randomized clinical controlled trials.
BY MR. GAGE:
Q. I'm talking about the third sentence.
A. Yeah, the information part.
Q. "Information on the clinical performance of mesh for pelvic floor repairs is available in the published literature," now, you and I agree that sentence doesn't specifically relate to Prolift+M?
A. Well, it's a garbage statement. I mean, it's a garbage statement --
Q. That was where I was headed is is --
A. It's a throw-out statement that you would give to a surgeon. Well, there's published literature on mesh. You don't think any surgeon already knows that.
And so it really just -- it distracts from what the FDA's message was, that, yeah, there's mesh literature. Contact your sales rep. So it's basically taking away the thrust of the warning that the surgeon would have had that, beware, there's no information about this product.
Q. In your opinion, should a surgeon implanting a Prolift+M consult the medical literature concerning mesh for pelvic floor repair before

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implanting Prolift+M?
A. Not necessarily. They don't have time to do that. Surgeons are fairly busy, and they rely on the sales reps to give them the important information, which is what it says here, "Contact your sales rep."
But I think it's just -- it's a gratuitous statement to say, yeah, there's pelvic mesh literature. It has nothing to do with Prolift+M.
Q. So in the context of Prolift+M, when the device first comes on the market, it's your opinion there was no published literature regarding its performance?
A. And that's what FDA wanted out there. They didn't want it to rely on Prolift. They wanted it to be separate, that there was no literature for Prolift+M.
Q. All right.
A. And that was -- and then we went to the negotiation back and forth between -- and there's nothing wrong with negotiation. Manufacturers do it all the time.
But in terms of adequate conveying to a surgeon, it watered it down so that the information would be lost.

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Q. Do you know why FDA or does FDA share your opinion that it was watered down and it was a trash statement -- or, excuse me.
Was it FDA's opinion that this was garbage information and was a throwaway statement?
A. Actually, if you read in my report, it was at the very end, that they were under a time constraint to get their MDUFA date. And so they negotiated. And from an FDA's point of view, it's better to get that in than not have anything at all.
So from a public health, they're trying to negotiate what they could do in a MDUFA time frame, and they wanted to get this done. And so they accepted it. Nobody argues that they accepted it, but it was a much more robust request by the FDA just to have that one line all by itself.
Q. All right. Let's go down to adverse reactions.
Do you see those?
A. Yes, sir.
Q. Do you recall having read the adverse reactions section of this Prolift+M IFU before today?
A. Yes, sir.
Q. Where did you read it?

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A. In terms of the 510(k), there was information about the Prolift+M, and then the discussion back and forth with the FDA as to those sections. So it was primarily in the 510(k).
Q. It says, "Potential" -- the first bullet says, "Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, ureter -- urinary retention/obstruction, ureter obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, or current prolapse, inflammation, adhesion formation, fistula formation, contracture or scarring, and mesh exposure, erosion, or extrusion."
Did I read that correctly?
A. Yes, you did.
Q. What do those words communicate to a pelvic floor surgeon?
A. Nothing specific about Prolift+M. They would look at that and they would go, those are all the things that typically can occur after urinary surgery.
But it's not specifically -- it's not robust when it doesn't say, "This has been reported for

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this product." You know, "We have risks of this."
And we think of this, particularly as this product was on the market, that it should have been updated with, what is the report of urinary retention with Prolift+M? How frequent is it occurring?
So you're going to have a list of things here, but it's not going to mean anything to the doctor because he's going to go, "Oh, yeah. I know these things can happen when you use mesh."
Q. If the frequency -- I take it your one -- your criticism there is there's no product-specific frequency in the adverse reactions section; correct?
MR. JONES: Objection.
THE WITNESS: That would be, and it would be something -- when this first came out --
BY MR. GAGE:
Q. Could you just answer -- would you answer that?
A. Yes.
Q. And if you could answer it "yes," and then give your explanation, I think that would be helpful.
A. Well, yes. But the thing is -- I will give them, when they first went on the market, they

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didn't have that information. But then for a 510(k), they can immediately update their information with the -- with the postmarket performance of this product.
Q. Should a pelvic floor surgeon implant a mesh device if they don't have any frequency data with regard to adverse events specific to that device?
MR. JONES: Objection.
THE WITNESS: Well, that's what the -- that's what the line up there about, "There's no safety and efficacy information about this product." I mean, that should give a surgeon a little bit of pause if they really realize that there was no information about these risks.
You know, in terms of that, that would -- in terms of some other product, it should make a physician think about it.
BY MR. GAGE:
Q. So a surgeon reading this IFU would know it's not -- the Prolift+M has not been tested; correct?
MR. AYLSTOCK: Objection to form.
THE WITNESS: No, not the way they go on about the mesh stuff and then right underneath they're going to be talking about Prolift.

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BY MR. GAGE:
Q. I'm sorry.
A surgeon reading this Prolift+M IFU would know that there have been no randomized clinical trials involving Prolift+M?
A. That's what they have up in that first line and then if you look underneath --
Q. Hang on. Let me --
MR. AYLSTOCK: Let her finish.
THE WITNESS: If you look underneath, they go on and start talking about clinical performance for Prolift.
Now, remember, FDA had asked that the company not put Prolift in this because they look at these as two different products. But the company went ahead and put Prolift in here, which implies that somehow Prolift is going to somehow give the information for Prolift+M.
MR. GAGE: I move to strike everything after the initial response to the question.
BY MR. GAGE:
Q. Would a surgeon reading the Prolift+M IFU know from reading this IFU that Prolift+M had not been studied in randomized clinical trials? Yes or no? If you can answer that yes or no.

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A. Well, we have that statement up there --
Q. Can you answer that --
A. -- so yes.
Q. -- can you answer that yes or no?
MR. JONES: Objection.
THE WITNESS: Well, I can't speak for what any one surgeon would know, but I can speak as a regulatory expert.
BY MR. GAGE:
Q. Dr. Parisian --
MR. JONES: Let her finish.
THE WITNESS: There's only one statement there, so they would know from that one statement that it's not been in randomized controlled studies, yes.
BY MR. GAGE:
Q. Thank you.
A. But then they go on to talk about the clinical performance, and it implies that Prolift is translatable to Prolift+M, which we know it's not, and so it's misleading.
We have one statement up above where it says there's no randomized control. Then we have mesh literature being referenced. So any one physician, I can't speak for what they would know, but I can

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say, from the way it's designed as a regulatory expert or an FDA and a physician, it's misleading. It's -- it's vague. It's like you don't understand what's going on here.
Q. So you don't believe -- I just want to make sure I understand, because I'm struggling to understand you -- that a surgeon who reads the sentence, quote, The safety and effectiveness of the Gynecare Prolift+M system compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials, period, closed quote --
MR. JONES: Objection.
BY MR. GAGE:
Q. -- that a surgeon reading that sentence would -- would, because of additional sentences, believe that the device had been studied in randomized controlled clinical trials?
MR. JONES: Objection.
THE WITNESS: You see in -- no. A surgeon would believe that there was no randomized well-controlled study, yes.
BY MR. GAGE:
Q. That was my question.
A. But this is a medical device in surgery, and

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they're not usually studied that way. So it really is kind of like a statement, like, what does it mean when you go on and then you talk about the mesh literature, you're talking about the clinical performance below, so it's confusing.
Yes, but surgical devices are not usually studied in randomized well-controlled studies.
MR. GAGE: All right. Move to strike everything after the word "but."
That -- that was -- thank you. I finally now understand.
BY MR. GAGE:
Q. All right. Now, Dr. Parisian, with regard to the adverse reactions, would a surgeon understand from reading this Prolift+M IFU that he or she, if they chose to implant a Prolift+M, if all they consulted was the Prolift+M IFU, they would be implanting a device without knowledge of the frequency of the adverse events that are listed in the adverse reactions section?
A. Can you say that again?
Q. Yeah.
Would a -- would a surgeon reading this Prolift+M IFU have any information about the frequency of adverse events from reading this

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Prolift+M IFU?
A. No.
Q. So if a surgeon chose to implant a Prolift+M IFU, they would have to go elsewhere for information about the frequency of those adverse events; correct?
MR. JONES: Objection.
THE WITNESS: No. They're supposed to have it in the label. An adequate label should have it.
MR. GAGE: Move to strike. It's not responsive.
Could you repeat the question?
(Requested portion was read by the Court Reporter.)
MR. JONES: Same objection.
THE WITNESS: No. Because if you -- if you look -- if, one, they required an adequate label, and, No. 2, if you look at the potential adverse reactions, nothing is there about chronic.
I mean, surgeons would think that a lot of this stuff are acute, but there's nothing about these being chronic.
MR. GAGE: Excuse me, Dr. Parisian. I have to move to strike the answer as nonresponsive.

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Could you read the question back?
And I'm going to say, if the witness persists, I'm going to have to ask for more time.
MR. JONES: She's answering the question.
MR. GAGE: No, she's not. Not even close.
MR. AYLSTOCK: She's absolutely answering the question.
MR. GAGE: Not even close.
So could you read the question back one more time?
(Requested portion was read by the Court Reporter.)
MR. JONES: Objection.
THE WITNESS: Yes, they would, because they're certainly not in the label. It's not an adequate label.
MR. GAGE: Move to strike everything after the word "yes."
BY MR. GAGE:
Q. And is it your opinion that the adverse reactions that are listed in the Prolift+M IFU do not communicate that those are potential risks of the Prolift+M?

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A. Yes.
Q. Okay.
A. And that they can be chronic, not just acute, because that list is primarily acute complications post-surgery.
MR. GAGE: Move to strike everything after the word "yes" as nonresponsive.
BY MR. GAGE:
Q. Dr. Parisian, do you -- you've looked at a number of mesh IFUs in connection with your expert work. Is that correct?
A. Yes, sir.
Q. Have you found one that's adequate?
A. Not in the cases I've been involved. I haven't looked at every single one. I haven't looked at every single one. I'm not involved in every single case, so . . .
Q. Of the IFUs that you have looked at, have you found any that are adequate?
A. No. Not -- not the cases I've taken, no.
Q. Have you found any that have frequency data with regard to adverse events?
A. I don't recall.
Q. Can you point me to any medical device IFU for any type of a medical device that you believe is

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adequate?
A. You know, I haven't -- yeah, there's lots of devices that I have not been involved in. I mean, there's adequate labels.
Are you saying that every device in the company -- country? I don't know.
Q. Dr. Parisian, I'm asking you a question.
Can you identify -- well, read the question back.
(Requested portion was read by the Court Reporter.)
THE WITNESS: I'm sure there's lots. I haven't developed that.
BY MR. GAGE:
Q. Okay. After Prolift+M was cleared, did FDA ever recommend any labeling changes for Prolift+M IFU or patient brochure?
A. I don't recall that they did.
Q. Has FDA ever determined that the Prolift+M IFU or patient brochure were false or misleading?
A. Not that I'm aware of in terms of writing, and you're talking about a letter or something. I haven't seen a letter to that effect.
Q. Has FDA ever declared the Prolift+M IFU or patient brochure to be inadequate after the device

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was cleared?
A. After it was cleared, no. I haven't seen anything from the FDA.
Q. And FDA has never determined the Prolift+M device was misbranded or adulterated; correct?
A. Correct. There's no official ruling like that, yes, sir.
Q. Does FDA have the power to make a device manufacturer change the wording in its IFU or patient brochure?
MR. JONES: Objection.
THE WITNESS: The power? They have the authority. Do they ever use it? No. They try to get voluntary compliance.
BY MR. GAGE:
Q. Has Ethicon -- I'm sorry. Strike that.
Has FDA ever concluded that Ethicon failed to provide safety information to FDA that was pertinent to Prolift+M?
A. Well, the Prolift. That was a 510(k), remember, that they were asking for the Prolift -- they hadn't given them the clinical trials, so there's some interaction there. They didn't do a ruling or some kind of a document, but they did make them give them the information for it.

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Q. I think my question, though, was specific to Prolift+M.
A. Right.
But Prolift fed into Prolift+M in terms of the 510(k), because they said that it wasn't the predicate. They made them give the French information, the other studies.
Q. Let me ask the question a different way.
A. Okay.
Q. After May of 2008, did FDA ever conclude that Ethicon failed to provide safety information to FDA that was pertinent to Prolift+M?
A. Not that I've seen.
Q. Did FDA ever request or order that Prolift+M be withdrawn from the market?
A. No.
Q. Did FDA ever declare the Prolift+M was illegally marketed?
A. No.
Q. And we can agree FDA never recalled Prolift+M?
A. Well, the FDA very rarely recalls anything, but it was never recalled by Johnson & Johnson.
Q. Was Prolift+M ever recalled by the FDA?
A. No.

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Q. Did FDA ever determine that Prolift+M was not safe and effective?
MR. JONES: Objection.
THE WITNESS: Well, it was cleared. That was the only interaction with the FDA. FDA cleared it. So there's no debate that the FDA cleared it.
BY MR. GAGE:
Q. Now, Dr. Parisian, you indicated -- you mentioned in your report you had some information about the 522 studies.
Do you remember that?
A. Yes, sir.
Q. Had Ethicon chosen to conduct the studies that FDA requested with regard to Prolift+M, is it correct that the Prolift+M device would have remained on the market while those studies were underway?
A. You know, in terms of the 522, I don't think that's specified. You could have done a postmarket study for women who were implanted. You didn't need to keep marketing the Prolift+M.
The company chose to pull it off the market and asked FDA to put it on hold. But if you look at the 522 process, it doesn't have to be commercially

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marketed.
Q. Could -- could Ethicon have continued to market the Prolift+M while conducting the 522 studies?
A. They could have. They would have been required to. If they continued to market it, they would have had to do the 522 studies.
Pulling it off allowed them to put it on hold basically, and -- and FDA had enough on their plate with the other studies, they didn't force them to do a postmarket study on the Prolift+M.
Q. So FDA could have permitted Ethicon to continue marketing Prolift+M while the 522 studies were being conducted on Prolift+M; correct?
A. Yeah, sure. That's not saying the FDA wanted them to, but it is a 510(k) cleared device.
Q. Have you looked at any of the studies that other manufacturers have done in response to the 522 orders?
A. I've been looking at them, yeah. What do you want to know?
Q. Well, I mean, have some of the manufactures completed those studies?
A. I don't think they've completed them, and some of them are working with the physician groups

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to try to get information, postmarket information.
I mean, in terms of the POP, they're going to have to come out with a PMA, so all the manufacturers of a POP device are going to have to come out --
Q. What -- what devices have you seen 522 studies or 522 interim results for thus far?
A. I don't recall which ones that I've seen offhand. I think -- I thought Boston Scientific I saw some, but I don't remember. I haven't looked at them.
Q. Have you spoken with any patients who have had a Prolift or a Prolift+M implanted in them?
A. No.
Q. And I assume you have not conducted any study or survey of women to determine what risks they may have been aware of as a result of reading the Prolift+M patient brochure?
A. That's correct. I haven't done a study like that.
Q. Do you know how many mesh manufacturers have patient brochures?
A. No, I don't know how many.
Q. Do you know if any of the manufacturers -- well, let me ask you this: You're working in cases

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against Boston Scientific and Bard and AMS; correct?
A. Not Bard.
Q. Boston Scientific and AMS?
A. AMS.
Q. And Ethicon?
A. And Ethicon.
Q. Did Boston Scientific or AMS have patient brochures for their pelvic organ prolapse devices?
A. I believe so.
And then all around 2008, their patient brochures were changing because FDA was trying to get information -- negotiate information into the labels.
So they've all had brochures, but 2008 seems to be when FDA was pushing to try to update it with what at least was in the medical literature.
Q. Did you compare the Ethicon patient brochure for Prolift+M to any other manufacturer's pelvic organ prolapse patient brochure?
A. No.
Q. Do you know if the FDA ever commented on the adequacy or the inadequacy of the Prolift+M patient brochure?
A. No, I don't remember seeing them comment on it.

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Q. Dr. Parisian, I'll represent to you, with regard to Prolift -- and I'm not -- and I'm meaning specifically the Prolift, not Prolift+M. Okay?
I'll represent to you that there are in excess of 3- to 400 studies of different types on the Prolift device.
Does that surprise you?
MR. JONES: Objection.
THE WITNESS: No.
BY MR. GAGE:
Q. On your reliance list, I saw that you had approximately 15 of those studies.
Have you -- does that sound about right to you?
A. Probably.
Q. Have you endeavored to look at the other studies that are out there on Prolift?
MR. JONES: Objection.
THE WITNESS: No.
BY MR. GAGE:
Q. All right. Dr. Parisian, continuing, do you have any opinions about the process that led to the classification of surgical mesh in 1988?
A. Do I have an opinion? No. I mean, it's just a fact it was a pre-amendment classification.

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The pre-amendment device classified Class 2 in 1988. No. It's just a fact.
Q. Dr. Parisian, you indicated in your report that --
A. Where are you?
Q. Well, I'll read it to you.
It says -- it's Paragraph 41. You say, "When Ethicon submitted the original Prolift+M 510(k), FDA's ODE reviewers became aware that Prolift had marketed, quote, off label, closed quote, for years by Ethicon for POP without 510(k) clearance or an FDA-approved IDE. Yet, the premarket ODE branch pursued no official regulatory action or civil penalties against Ethicon for its violation of the act. ODE permitted Ethicon to add Prolift to its Prolift+M 510(k) submission. This was done at the regulatory discretion of the ODE review branch, and in the past, is a decision based on FDA resources and cost to the public."
Do you see that?
A. Um-hmm.
Q. When you say "this was done" -- "this was done at the regulatory discretion of the ODE review branch, and is, in the past, a decision based on FDA's resources and cost to the public," does the

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word "this" mean FDA allowing Ethicon to add Prolift to the Prolift+M 510(k)?
A. Yes, sir.
Q. Okay. In the preceding sentence, you say, "The premarket ODE branch pursued no official regulatory action or civil penalties against Ethicon for its violation of the act," do you know why they chose to not do that?
A. It takes a lot of time and effort and resources, like I said. It's just their choice.
You could have -- you could have not done that. That was what their choice was. Do I know why? No. That's how they chose to handle it.
Q. Does FDA's perception of the company's acting in good faith or lack of acting in good faith factor into that discretion?
A. No. A lot of it has to do with the effort that it would take to bring some kind of a regulatory action. This way, we can just -- in terms of the process, they can just clear the 510(k).
Q. Okay. So could -- I'm going to ask the question again. I'm going to ask the court reporter to ask that question again because I'm not sure you -- if you will listen very specifically to the

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wording of it. I want to make sure that you heard it and you are answering that particular question.

(Requested portion was read by the Court Reporter.)

THE WITNESS: Not necessarily from my experience. Usually it is, what is the company -- I can't make what the intent of the FDA was. It's a fact that they did that.

Have I seen situations in the past when I was there and they did that? Yes, but it's not necessarily what the company's -- what the FDA is thinking about the company.

It's basically, what would be the effort that it would take to bring a regulatory action against the company, what does it solve, and so they just chose this path.

BY MR. GAGE:

Q. Have you seen any statements from FDA about whether FDA believed Ethicon was acting in good faith with regard to this issue?

A. Not at the time. That's why I looked at that document that we have from 2007, 2008, when the FDA was talking about -- they were specifically focusing on Ethicon.

Q. And just to be clear, you're talking about

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the -- Exhibit 6?

A. Right.

Q. Okay.

A. And so at that time, I don't see where they're talking anything about good faith. They're talking about that the product had been marketed, and FDA was trying to figure out how to catch up with this issue.

So there may be some statement somewhere, but from the documents that I saw, there wasn't anything in this period of time.

Q. Okay. So if there is such a statement, you haven't seen it?

A. I haven't seen it, and I would have to look at it and put it in context with what was going on. But also having been there, I know that ODE is not one to usually trigger a compliance action, which would have been Office of Compliance postmarket.

Q. In your report in several places, you discuss that certain certifications signed by Ethicon were not in compliance with regulations according to you.

Do you recall those statements?

A. I didn't say noncompliance, but they're not consistent with what the normal statement is, and

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they've been changed. They've been altered. And if you were at FDA, you would hardly ever read those things to see that they've been altered, but these were.

Q. On page 71 of your report in Paragraph 197, you have a sentence that says, "Without any explanation, or perhaps as an error in typing, Ethicon changed the statement in the original 510(k) submitted June 2007 and repeated the same error in wording and certification in its submission of September 19, 2007, significantly narrowing the truthful and accuracy scope only to the SE decision."

A. Yes.

Q. Do you recall that?

A. Yes. And I stated there that I don't know why it occurred, so I don't know why it occurred. But whatever it is, it seems to be occurring in their 510(k)s, and it did narrow the scope to that no material fact for the substantial equivalence decision had not been provided.

Q. Have any of the documents that you have reviewed since you wrote this report or any of the information you may have received to gather, investigate, or research since you wrote this report

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given you any additional information that would allow you to say one way or the other as to whether that was an error in typing or whether it was something other than an error in typing?

A. No.

Q. In Paragraph 231 on page 83 of your report, you say, "Thus, PFR and use of laser cutting of PE mesh into new complex shapes introduced new and unaddressed issues of safety and effectiveness for PFR not seen with TVT, SUI, or the AMS predicates. These new issues were not studied by Ethicon."

Do you remember that?

A. Yes, sir.

Q. Have you seen any clinical data that indicates that laser cut mesh is dangerous to patients?

A. No. It's just -- in terms of the laser cut mesh, it changes the edge in terms of the -- the potential for rubbing. It's just -- it's not like you're going to see laser cut is dangerous. It's something you need to consider in terms of the forces and the change in the plastic mesh.

I mean, it's just a visual difference between machine cut and laser cut mesh.

Q. But you have not seen any clinical data

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comparing laser cut to machine cut mesh in terms of patient outcomes, have you?
A. I haven't looked for that in terms of POP. It is a difference between TVT, TVT-O, and TVT-S, and also in terms of the difference for a Prolift. So it's something to be considered in terms of design.
Q. Dr. Parisian, you're generally aware that the -- and I believe you've mentioned in your report in various places that plaintiffs allege, and I believe you have opinions that address certain alleged defects in the mesh itself, such as the propensity of the mesh to cause excessive inflammation. Is that -- I mean, that's one of your opinions; correct?
A. Where are you getting that opinion from, I mean, because I know that there's going to be other people talking about the mesh properties?
But in terms of the inflammatory response that you have in patients, are you looking at a specific thing in my report?
Q. I think in your TVT-Secur report, you indicated issues like pore size, weight -- pore size and weight of the mesh as being issues for your TVT-Secur?

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A. I mean, you're talking about that one table, I think, on page 48?
Q. I don't have the specific -- I've got it --
A. Those -- those are the evolution -- I think where -- and if that's one table that you're thinking of, I think that's just the evolution of mesh is basically -- because TVT is just your basic old PROLENE mesh, which is a heavy mesh with a --
Q. I'll tell you what. Let me -- let me move -- because my time is limited, I want to keep moving here, so let me ask it in a different way.
Is PROLENE mesh -- can PROLENE mesh be used in the United States for pelvic organ prolapse repair?
A. Well, it is right now, TVT, TVT-O.
Q. Well, that's stress urinary incontinence. I'm talking about the pelvic organ prolapse.
A. Oh, pelvic organ prolapse? Right now I don't think the company is selling it. Is it? I mean, they don't have a product with PROLENE mesh.
Q. You're familiar with GYNEMESH PS?
A. Right.
Q. And ARTISYN?
A. Right. And those are put in abdominally.
Q. Correct.

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A. They're not put in intra-vaginally.
Q. Correct.
A. So, yes, you can use it intra-abdominally.
Q. And that's acceptable with FDA; correct?
A. Right now it is because the FDA has only made the 522s occur for the transvaginal mesh.
Q. Right.
There are no 522 orders for the abdominal meshes; correct?
A. Not that I'm aware of.
Q. Do you know if GYNEMESH PS is made of the same material that is found in Prolift+M?
MR. JONES: Objection.
THE WITNESS: Well, the Prolift is GYNEMESH PS. Prolift+M is -- is different. It's ULTRAPRO. And so it's -- it's kind of -- with the Monocryl that's woven into the underlying mesh. Neither one of them are PROLENE. PROLENE is the TVT-S, the T- -- the TVT family is PROLENE.
BY MR. GAGE:
Q. Is Prolift+M made of PROLENE?
A. It's ULTRAPRO, which is -- I mean, they're all polypropylene, but it's a different weave and a different mesh than polypropylene, because supposedly when the Monocryl is gone, you have a

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lighter weight mesh. You have also more of the bigger pores when the Monocryl's gone. I think it's like 20 to 30 grams per millimeter squared.
Q. Is the polypropylene in Prolift+M PROLENE, or is it some other substance?
MR. JONES: Objection.
THE WITNESS: Well, they're all polypropylene. They're all the same resin source, which would be your Phillips, Chevron, whatever, polypropylene. So it's -- it's all that same resin.
It's just you change your mesh in terms of your weave. Like, if you take GYNEMESH PS, it's a lighter mesh so -- but the very original mother of all of this was PROLENE, which is your heavier mesh. And I think it only has a porosity of 49 percent porous compared to the mesh fabric.
BY MR. GAGE:
Q. Are there any differences in the chemical makeup of the polypropylene and PROLENE in Prolift+M as compared to Prolift or TVT?
MR. JONES: Objection.
THE WITNESS: Well, they're all polypropylene. Is that what you're asking me?
BY MR. GAGE:
Q. Are they all the same type of polypropylene?

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MR. JONES: At what point?
THE WITNESS: Well, they're not all -- they're different weaves. They're different families.
BY MR. GAGE:
Q. I'm not talking about weave. I'm talking about the chemical makeup.
Is the -- is the polypropylene in Prolift+M made of the same chemicals and substances that are found in the polypropylene in Prolift and TVT?
MR. JONES: Objection.
THE WITNESS: Right. It's the same resin, polypropylene resin.
BY MR. GAGE:
Q. All right. What do you make, if anything, of the fact that the FDA permits the use of PROLENE mesh for pelvic organ prolapse repair abdominally?
A. Oh, I know -- I mean, in terms of -- it's a long, tortious history. Remember, surgical mesh began as a pre-amendment device.
Q. I'll withdraw the question.
Dr. Parisian, are you familiar with the phrase "valid scientific evidence"?
A. Yeah.
Q. Dr. Parisian, in order for a new mesh device

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to be adequately tested for permanent implantation in women, does it need to be supported by valid scientific evidence?
A. Did you say for POP?
Q. I'll withdraw the question and re-ask it.
Dr. Parisian, in order for a new mesh device for pelvic organ prolapse to be adequately tested for permanent implantation in women, does it need to be supported by valid scientific evidence?
A. Not yet. It will when they have to do a PMA for a POP device.
Q. Would it be reasonable for a manufacturer of a new pelvic organ prolapse mesh device to test it in women before it's marketed?
A. It depends. It depends. Because the FDA is still going to probably allow them to -- since polypropylene is grandfathered in, they're going to allow them not to specifically look at that mesh, because that's the way the FDA is, and you can start with animal studies before you go to humans. And so --
Q. Well, if you have a new polypropylene mesh device that you wanted to market, do you believe it should be tested in live women before it's marketed?
A. It depends. I mean, I would start with

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animals first before I go and jump into women.
Q. All right. If animal studies are done, do you believe that women -- female studies should be done before it's marketed?
A. Well, yes, to get robust information in terms of your valid evidence, that you would have a situation where you actually are monitoring the women and you can test, and you get the data from them, so it's more robust.
The 510(k) process allowed them not to have that, but it would be more robust for a manufacturer to have that information.
Q. Do you know how many women would need to be the subject of a clinical study using that new mesh design before it could be declared safe and effective?
A. No. Because that would -- if you're talking about safe and effective, you're talking about a PMA, and I don't know what the FDA is going to say in terms of the PMA for these products.
Q. Do you know how long such a study should last?
A. No. I don't know how -- I don't know how long FDA is going to -- they usually will --
Q. Well, putting aside the FDA, I'm talking

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just you, Suzanne Parisian, Dr. Parisian --
A. Okay.
Q. -- with your experience and your talent, can you tell me how long such a study should be conducted in live women before a new mesh POP device is marketed?
MR. JONES: Objection.
THE WITNESS: Well, it's going to be a minimum of a year. I mean, you need to have a year at least, and then usually you're going to have at least five years data accumulated. The FDA may clear something before that.
Remember, all these devices, FDA, when I've seen what they're trying to say, all these devices had long histories. So the FDA has been encouraging the people doing the 522s, if you're going to want a PMA, that you actually incorporate your current product that you're using in order to have longer term data, five-year data, when you come in with a PMA.
BY MR. GAGE:
Q. Dr. Parisian, did you endeavor to gather MAUDE reports on Prolift+M?
A. No.
Q. So is it fair to say that you are not going

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to render an opinion that specific issue reports or specific patient events regarding Prolift+M were not properly reported to FDA by Ethicon?
A. I haven't looked for specific events. I think what was more would be the IFU. What was it the company knew internally and what should they have put in their IFU.
Q. Have you undertaken a review or an analysis of the company's issue reports with regard to Prolift+M?
A. I don't believe I have.
Q. Okay.
A. Because you're talking about like the complaint files and the CAPA?
Q. Yes.
A. I haven't looked at all that.
Q. Dr. Parisian, you are -- well, let me ask you this: Dr. Parisian, have you seen any of the television advertisements with regards to pelvic mesh?
A. I see something pop up on television. Nothing specific.
Q. Have you examined that issue in connection with your work for any of the mesh litigation that you're involved in?

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A. No.
Q. Does -- do -- does mesh advertising potentially bias a patient in favor of reporting or seeking legal counsel?
A. I don't know.
Q. Have you looked at any of those issues with regard to lawyer advertising?
A. No.
Q. Have you attempted to examine how many lawsuits have been filed regarding Prolift+M?
A. No.
Q. All right.
MR. GAGE: Can we just go off the record for a second?
(Recess taken.)
(Whereupon, Exhibit No. 18 was marked for identification.)
BY MR. GAGE:
Q. Dr. Parisian, I'm going to hand you a document marked as Exhibit No. 18.
A. Thank you.
Q. Have you ever seen that document before?
A. Yes.
Q. What is that document?
A. That is a Gynecare, and it's got Prolift+M,

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and it's a patient brochure.
Q. Was this among the documents that you -- as I understand it -- strike that.
As I understand it, there have been several versions of various patient brochures that you've reviewed; correct?
A. Yes, sir.
Q. Do you know which ones pertain specifically to Prolift versus -- Prolift+M as opposed to other of the Ethicon devices?
A. No.
I was trying to get what date this was.
Q. So why don't you flip through this one?
A. This one is in color. See, I haven't seen them in color.
Q. Why don't you flip through this one?
A. Okay.
Q. And when you've had a chance to flip through it, just let me know.
A. Okay.
Q. Have you had a chance?
A. Yes, sir.
Q. Okay. Have you seen this specific patient brochure before?
A. I don't know if I've seen this one. I've

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seen something like this one. I don't know what the Prosima is.
Q. Okay. So if this document does not appear on your reliance list, would it be fair to say that this is the first time you've seen this specific patient brochure?
MR. JONES: Objection.
MR. AYLSTOCK: Objection to form.
THE WITNESS: This one, yes. In color, yes. I've seen a patient brochure but usually they're drafts are what I've seen from the 510(k).
BY MR. GAGE:
Q. All right. If we -- let me ask the same question, if we took the color out, have you seen this patient brochure in its -- in its black and white version?
A. I may have because the pictures of the people look familiar.
Q. If the -- if your reliance list does not contain this document, would it be fair to say that today is the first time you've seen this specific patient brochure?
MR. JONES: Objection.
MR. AYLSTOCK: Objection to form.
THE WITNESS: If it's not in the

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510(k) -- because there is something in the 510(k) about their -- their patient brochure, I think, so I've seen something, but I don't know. This one may be the first time, yes.
BY MR. GAGE:
Q. All right. Dr. Parisian --
A. No questions?
Q. Oh, just a couple more. My last few minutes here. I want to go back to the concept of valid scientific evidence.
Dr. Parisian, are well-controlled investigations considered to be valid scientific evidence?
A. Yes, but then it goes down a hierarchy, because in terms of the FDA's definition, they can go down to like case studies and stuff, so --
Q. I'll read them to you. We'll kind of take it one at a time.
Does valid -- valid scientific evidence may include a well-designed randomized clinical trial?
A. Yes.
Q. Valid scientific evidence may include partially controlled studies?
A. Yes.
Q. Valid scientific evidence may include

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studies and objective trials without match controls?
A. Yes.
Q. And valid scientific evidence may include well-documented case histories conducted by qualified experts?
A. Yes.
Q. And valid scientific evidence may include reports of significant human experience with a marketed device from which it can fairly and responsibly be concluded that there's a reasonable assurance of safety and effectiveness of a device under its conditions of use; correct?
MR. GAGE: Objection to form.
THE WITNESS: Yes.
MR. GAGE: Is that because I read it too quickly?
MR. AYLSTOCK: I couldn't understand what that --
MR. GAGE: She understands it because she knows it's a specific regulatory definition.
THE WITNESS: Right.
BY MR. GAGE:
Q. Would you agree that the following are not considered valid scientific evidence to show safety or effectiveness: Isolated case reports?

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A. Valid -- because they can be used for safety. Any -- any patient and human experience can be used for safety.
Q. Let me ask the question a different way.
Would you agree that the FDA does not consider valid scientific evidence -- strike that.
Would you agree that the FDA does not consider isolated case reports as valid scientific evidence to show safety or effectiveness?
A. For effectiveness particularly, but they will consider them for safety. You get to decide.
Q. Do you agree that the FDA does not consider random experience as valid scientific evidence to show safety or effectiveness?
A. Effectiveness particularly, because remember, that's the key is what they clear things on or approve it on is effectiveness. So, yeah, that's not going to cut it for effectiveness, but safety it may.
Q. Well, the FDA doesn't consider isolated case reports or random experience as valid scientific evidence to show safety.
Would you agree or disagree with that?
A. I disagree with that, because of postmarket surveillance. You have to use that information to

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come up with the postmarket information.
Q. I think -- I think --
A. You're not going to approve it or clear it on random case things, but you still consider the safety information.
Q. I think that may be where we're missing, and I think when we talk about showing safety or effectiveness, we're talking about the definition under a 510(k).
A. Yeah.
But, remember, most things are showing effectiveness in terms of clearance and approval. Safety is harder to demonstrate.
And so everything about a use of a product can relate to safety, and that's why your postmarket surveillance, obviously, you update your levels based on safety information from various sources, including it could be a case report, so -- so safety is a little different than efficacy.
Q. Would you agree that the FDA does not consider unsubstantiated opinions to be valid scientific evidence to show safety and effectiveness?
A. Yeah. Again, for clearance and approval.
Q. Dr. Parisian, do you understand Prolift+M to

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have larger pores and less weight than Prolift?
A. That's theoretically what it's supposed to be. It's GYNEMESH, but then they've put in the -- the Monocryl, and so supposedly when the Monocryl is gone, you have a lighter weight mesh. It's supposed to be 20 to 30 grams some -- and so theoretically it's going to be lighter weight when that Monocryl has gone away.
Q. Do you believe that Prolift+M is more safe or less safe than Prolift?
MR. JONES: Objection.
THE WITNESS: You know, I don't know. I don't have an opinion. I think -- I don't have any -- I mean, in terms of the 510(k), there was less data about Prolift+M than there was about Prolift, both of which seemed to have problems.
Prolift definitely had problems, but that was what the FDA was saying. They didn't know that Prolift+M was more safe. I mean, there's no data to support it.
MR. AYLSTOCK: I think we're done.
MR. GAGE: Yeah, we're done.
Well, we're done because my time is up.
(Concluded at 12:27 p.m., and then re-opened at 2:05 p.m.)

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(Whereupon, Exhibit No. 19 was marked for identification.)
BY MR. GAGE:
Q. All right. Dr. Parisian, counsel have all agreed to reopen the record on our concluded Prolift+M deposition so that we could cover a document that you forgot to bring to my attention earlier this morning that's pertinent to Prolift+M.
I'm handing you a document that -- or a collection of documents, actually, that I have marked collectively as Parisian Exhibit No. 19 to your Prolift+M deposition.
Could you tell me what those are?
A. Yes. And I thought I had given them to you this morning, but I hadn't.
It's the medical literatures, some of my searches that I have in my file for Prolift+M and about risk -- the French studies particularly.
And the reason I got confused is because the -- let me just take one document out of here because --
Q. And, Dr. Parisian, before you finish, are there other documents in my hand that need to be made part of that composite exhibit, because I've got a US Patent for knitted surgical mesh?

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A. No. That can be in there.
Q. I'm sorry?
A. That's PROLENE, so that's okay.
Q. So do you want -- okay. So I've got some patent and trademark information about PROLENE?
A. Right.
Q. I've got some stuff about Textile Development Associates. It's called polypropylene monofilament knitted mesh fabrics, a United States Patent, and then an ORDV 510(k) sterility review guidance?
A. Correct.
Q. Are these documents pertinent to your opinions on Prolift+M or just TVT-Secur or to both?
A. The TVT-Secur, yes. The sterility guidance, I don't think that really is an issue that we're talking about, so it just is in there. It's just one page, but -- and then the other document there that I gave you is for the Dura Patch.
Q. All right. And why don't we do it like this. Let me ask you -- and I'm going to -- since we only have one copy, I'm going to kind of come around and hover over you if you don't mind.
A. No problem.
Q. On Exhibit -- Parisian Exhibit No. 9 to your

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Prolift+M deposition, it looks to be a French study with some of your -- with some handwriting on it?
A. Right. It's my handwriting, my highlighting.
Q. All right. And you reference several times during your deposition a French study?
A. Yes, sir. And that's the French study.
Q. And this document purports to be the French study that you were referencing as you were testifying earlier this morning?
A. It is related to it. I went and got -- this is 2007, yes, but this is one of the French studies that I went and looked at.
Q. All right. Now, there's another document in this collection that's an abstract called "Mesh-related infections after pelvic organ prolapse repair surgery"?
A. Yes, sir.
Q. And what was the significance, if any, of this document to your Prolift+M opinions?
A. I was looking at the time, and it was about infection, and I didn't see that it was one of the ones that was in reference to the FDA. And it was an article about infection in vaginal meshes, so it was just basically looking at what information was

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available at that time.
Q. All right. And that's an abstract study, 2007?
A. 2007.
Q. And then -- all right. Let me just back up real quick.
For the French study and the 2007 abstract, are those documents that were provided to you by counsel, or are those documents that you got on your own research?
A. Oh, I got them. They're mine. This comes off the Ethicon Web site, and it's the -- it's the reference list for a physician, and so I went through the reference list looking to see, this would be information for a physician.
I guess I downloaded it -- when did I download it? December 2015. And I've highlighted the ones that were specifically due to vaginal mesh in this thing.
There's like 256 references, and there's only a few that are anything to do with vaginal mesh. Most of them were hernia.
You have that.
Q. All right. So the record is clear, Dr. Parisian, what we're talking about is a document

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that is within the collection of Exhibit No. 19, the first page of which is -- says at the top, "References Ethicon page 3 of 13"; correct?
A. Right.
And so if you go on the Ethicon Web site and you hit physician and then you hit references, this is the printout of 459 studies or references on the Ethicon Web site. And so it's for everything.
And so I went and looked to see how many of their 459 had anything to do with vaginal mesh, and 23 of them did, and that would be about roughly 5 percent.
Q. Okay.
A. So a physician if you went here, there's not a lot about vaginal mesh. It's mainly about bariatric surgery, hernia, but not much about mesh.
Q. And you did this review on December 16, 2015 --
A. Yes, sir.
Q. -- as evidenced by the date in the bottom right-hand corner?
A. Yes, sir.
Q. And do you understand this list to pertain to all products sold by Ethicon?
A. Yes, sir.

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Q. And these are my words, not yours, so correct me if I mistake.
But am I understanding this to be an omnibus listing of medical references that would pertain to the entirety of the Ethicon product line?
A. Yes.
Q. All right. And your purpose for going through that was simply to determine how many pertain to mesh and how many pertain to non-mesh devices by Ethicon?
A. That wasn't my reason. My reason was just that I was looking at the reference list to see what was in it. And then when I started looking at it, I went, gosh, there aren't many, and so I went through and I picked out the ones that were vaginal mesh.
Q. Are these -- what is a manufacturer supposed to do with regard to reference lists on a Web site? Is there some -- is there a standard or a regulatory expectation?
A. Well, you give them fair balance. Most of those articles are very positive, so if physicians went to their Web site and wanted to find out risk information, there's not risk information. Most of these are benefits. So it's not balanced in terms of giving a physician -- because like you were

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saying, physicians should go look up surgical mesh.
Q. Yes.
A. If you go to the Ethicon Web site, there's not a lot about risk. There's a lot about benefits. Most of these studies are benefits. The Nielson studies and here it is, Nielson 11 year, so if you were a surgeon, you're going to say, oh, look. It's pretty good. All this stuff is good stuff.
And so it's not -- in terms of fair balance, it's not giving you the risk information.
Q. All right. So if we go -- if we continue further in this document which is marked as collective Exhibit 19, I find another abstract, for lack of better pronunciation, Collinet, C-o-l-l-i-n-e-t --
A. Um-hmm.
Q. -- on Column A, article. Is that correct?
A. Um-hmm. Yes, sir.
Q. And the handwriting and the highlighting is yours?
A. Yes, sir.
So this is another French -- and so these are -- they're talking about risk factors, and this is a French article. That's why I'm looking at the abstract.

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But risk factors not referenced for the FDA, and then they're talking about the numbers that I have, 12.27 mesh exposures in two months, so I'm getting the information from this article, and that information was available in 2006 before the FDA even looked at the 510(k). And that information is not in there.

Q. Well, let me ask you this: Is this for Prolift+M or is this for Prolift?

A. This is for Prolift. Yeah, this is for Prolift because it was being done in France.

Q. Should the -- should the -- should Ethicon provide the FDA in its Prolift -- Prolift+M 510(k) the medical literature for Prolift?

MR. JONES: Objection. Are we -- are we -- I feel like we're getting into rehashing Prolift+M issues and not just marking an exhibit and asking her what she marked.

You're kind of getting into asking her -- to me, you're asking her now about substantive opinions outside of this exhibit that you're -- that we marked.

MR. GAGE: I mean, I know, but I mean, I didn't have the exhibit.

MR. JONES: I mean, you get what I'm

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getting at?

Are you getting close?

MR. GAGE: It's a quick Q and A.

THE WITNESS: My quick answer is yes, they should have because it is a Prolift, Prolift+M 510(k). And this was the history of what they're proposing to the FDA, so, yes, they should have.

BY MR. GAGE:

Q. Okay. Let me ask you this: If the 510(k)s had been separate, would you have expected Ethicon to submit with the Prolift+M 510(k) literature pertinent to Prolift?

A. Yeah --

MR. JONES: Objection.

THE WITNESS: -- because it's actually the predicate. They originally made it so that Prolift was the predicate. Well, this is -- the Prolift predicate has got this significant failure issue, so the FDA needs to know, are we making changes to Prolift+M because we're addressing the safety issues.

BY MR. GAGE:

Q. Okay. And when you say "failure," you're talking about the mesh exposure rate reported in this study?

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A. That's right.

Q. Okay. Did the -- okay. So here the next one says -- it's another abstract. It says, "Risk factors for prosthesis exposure in treatment of genital prolapse via the vaginal approach"?

A. Right.

Q. And you've got written on here, "Earlier -- not given." Is that correct?

A. That's correct.

Q. And this is an abstract authored by Belot, B-e-l-o-t; correct?

A. Right. And so this is more information that they would have had that they didn't provide to the FDA in their 510(k).

Q. Okay. Is the Collinet and the Belot abstracts, are those listed in that list of literature on the Ethicon Web site, or did you find those through like a PubMed search?

A. Oh, I did this on a PubMed search. They're not on the FDA's website. I mean, they're not on Ethicon's Web site, no. These are ones I found.

Q. Does FDA do PubMed searches when they get 510(k) applications?

A. No, no, because it's up to the manufacturer to do them; not the FDA. FDA had -- particularly at

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this period of time, they didn't really have access to the NIH.

If you look at that document in 2007 I had for the FDA, they actually talk about having people go get them articles from the library because there's a library at FDA. So they -- those reviewers don't do their own searches as a rule. They have somebody else that you have to go through to get stuff.

Q. Is that still the rule today?

A. I don't know. I mean, I don't know. I was -- but you can't -- it's not up to the FDA to go get the literature.

Q. Do you know what -- all right. So let's look at these documents.

This one was the -- what did you call it, the Dura --

A. The Dura Patch.

Q. Dura Patch?

A. This is a neurological patch here.

Q. All right.

MR. GAGE: So let me mark this as --

(Discussion off the record.)

BY MR. GAGE:

Q. All right. So have we now covered the

additional documents that you found and after we had concluded the Prolift+M deposition?

A. Yes, sir.

Q. Okay. So the documents that you handed me and marked to me, were those documents that you had at the time you wrote your Prolift+M deposition [sic], or were those documents that you got after you wrote your Prolift+M -- strike that.

With regard to Exhibit 19, were these documents that you had in your possession before you wrote your Prolift+M report or after you wrote it?

A. Before.

Q. Okay. All right.

MR. GAGE: Now I believe we can conclude the Prolift+M deposition and go back into the TVT-Secur deposition.

(Deposition concluded at 2:18 p.m.)

C E R T I F I C A T E

I, ALISA SMITH, Registered Professional Reporter, Arizona Certified Reporter, do hereby certify that, pursuant to notice, the deposition of SUZANNE PARISIAN, M.D. was duly taken on March 8, 2016, at 9:06 a.m. before me.

The said SUZANNE PARISIAN, M.D. was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me.

I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

____

Alisa Smith, RPR, AZ CR 50712

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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ACKNOWLEDGMENT OF DEPONENT

I, SUZANNE PARISIAN, M.D., do hereby acknowledge that I have read the foregoing pages, 5 through 178, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_______________________________ ______________

SUZANNE PARISIAN, M.D. DATE

Subscribed and sworn to before me this
_____ day of _________________, 20____.
My Commission expires: ____________________

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Notary Public

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